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Extended Research Article

Team-based motivational engagement intervention in young people with first-episode psychosis: the EYE-2 cluster RCT with economic and process evaluation

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This article

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Abstract

Background: Early Intervention in Psychosis services improves outcomes for young people with psychosis, but 25% disengage in the first 12 months with costs to their mental health.

Objectives: To refine a toolkit and training and evaluate effectiveness, implementation, and cost-effectiveness of the Early Youth Engagement-2 intervention to reduce disengagement.

Design: Cluster randomised controlled trial with economic and process evaluation.

Randomisation: Randomisation at team level stratified by site.

Masking: Research assistants, outcome assessors and statisticians were masked to treatment allocation for the primary disengagement and cost-effectiveness outcomes. Participants and teams administering the interventions were unmasked.

Setting: Twenty Early Intervention in Psychosis teams in five sites across England.

Participants: A total of 1027 young people (14–35 years) with first-episode psychosis (F20–29, 31; ICD-10); 20–282 Early Intervention in Psychosis staff.

Intervention Team-based motivational engagement (Early Youth Engagement-2) intervention, delivered by Early Intervention in Psychosis clinicians alongside standardised Early Intervention in Psychosis, supported by the implementation toolkit (training, website and booklet series).

Comparison: Standardised Early Intervention in Psychosis, including National Institute for Health and Care Excellence guidelines approved interventions.

Main outcome measures: Primary outcome – time to disengagement over 26 months (days from date of allocation to care co-ordinator to date of last contact following refusal to engage with service, or lack of response to contact for consecutive 3-month period). Secondary outcomes – mental health, recovery, quality of life, service use, at 6 and 12 months.

Economic outcomes – National Health Service mental healthcare costs, wider societal care costs, clinical and social outcomes over 12 months; cost-effectiveness.

Process evaluation outcomes – fidelity to the Early Youth Engagement-2 model, implementation process scores, therapeutic alliance, qualitative outcomes.

Results: Disengagement was 16% across both arms. The multivariable Cox regression on 1005 participants estimated an adjusted hazard ratio for Early Youth Engagement-2 + standardised Early Intervention in Psychosis (n = 652) versus standardised Early Intervention in Psychosis service alone (n = 375) of 1.07 (95% confidence interval 0.76 to 1.49; p = 0.713). There were no observed differences between arms for any secondary outcomes. The health economic evaluation indicated lower mean mental healthcare costs of −£788 (95% CI −£3571 to £1994) and marginally improved mental health states for intervention participants. Early Youth Engagement-2 participants spent 30 more days per year in education and training (95% CI 1.52 to 53.68; probability positive outcome for the intervention: 99%), but these outcomes must be viewed very cautiously as only 22% of the sample provided data. The process evaluation revealed heterogeneous implementation fidelity and constant pressure to adapt to widespread disruption from COVID-19. There was no effect on therapeutic alliance: the most likely active change mechanism was through psychoeducation.

Limitations: Lower than expected disengagement, high loss to follow-up and impact of COVID-19 on fidelity, implementation and outcomes.

Conclusions: In the primary clinical effectiveness analysis, 95% confidence limits ruled out a reduction of more than 24% in the risk of disengagement with the Early Youth Engagement-2 intervention. In a cost-effectiveness analysis, estimates fell in the direction of dominance of the Early Youth Engagement-2 intervention (reduced costs, marginally better mental health states).

Future work: Dissemination of the booklet and website resources and an adapted version of the model as stand-alone tools for use in good-practice routine Early Intervention in Psychosis care.

Study registration: This study is registered as ISRCTN 51629746.

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Glossary

Acceptance onto caseload The point at which a patient in an Early Intervention in Psychosis service is formally accepted on to the 3-year Early Intervention in Psychosis caseload.

Allocation to care co-ordinator The point at which a patient is allocated to a specific member of staff who will be their main point of contact and will co-ordinate their care.

Care co-ordinator/lead practitioner The role in the team designated to the person who is the main point of contact and who co-ordinates care for a patient. They are normally nurses, occupational therapists or social workers.

Care programme approach The name for a programme of care delivered by a secondary mental healthcare service. It involves support for people with severe mental illnesses in the community, based on care co-ordination, care planning and case management, and 6-monthly reviews. It is now transitioning into the Community Mental Health Framework.

Cultural Adaptation Framework This framework is designed to facilitate the adaptation of therapeutic approaches for diverse ethnic, spiritual and cultural backgrounds.

Early Intervention in Psychosis triangulation tool An online repository of data relating to Early Intervention in Psychosis service organisation, management and delivery characteristics across England.

Lockdown The first national lockdown of leisure, social and occupational activity in response to the COVID-19 pandemic.

Logic model A logic model is a conceptual framework, presented graphically and used in a process evaluation to describe the relationships between components in a system and/or a theory of change.

NHS England The body that provides leadership and promotes and supports high-quality health and care services in England.

NICE concordant interventions Interventions recommended by National Institute for Health and Care Excellence for the treatment of first-episode psychosis, that are expected to be delivered in an Early Intervention in Psychosis service.

Normalisation process theory A theoretical framework incorporating a set of theoretical constructs that identify, characterise and explain core mechanisms that motivate and shape implementation processes.

Process evaluation A process evaluation is a quantitative or qualitative evaluation that aims to provide a detailed understanding of contexts, mechanisms and processes that aid understanding of the implementation of a complex intervention.

S136 Section 136 is part of the Mental Health Act that gives police emergency powers, if they think you have a mental health problem, to hold someone in a place of safety for up to 24–36 hours until a mental health assessment has occurred.

Tweet chat A tweet chat is a live Twitter event, usually moderated and focused on a general topic.

List of abbreviations

A&E	accident and emergency
AD-SUS	adult service use schedule
ARMS	at-risk mental state
AWTS	Access and Waiting Time Standards
CAF	Cultural Adaptation Framework
CBT	cognitive–behavioural therapy
CCG	Clinical Commissioning Group
COVID-19	coronavirus-19
CPA	care programme approach
EIP	Early Intervention in Psychosis
EYE	Early Youth Engagement
EYE-2	Early Youth Engagement-2
F2F	face to face
FEP	first-episode psychosis
GP	general practitioner
HoNOS	Health of the Nation Outcome Scales
ITT	intention to treat
LEAP	Lived Experience Advisory Panel
LGBTQ	lesbian, gay, bisexual, transgender and queer or questioning
MAR	missing at random
MHC	mental health cluster
MI	motivational interviewing
NCAP	National Clinical Audit of Psychosis
NICE	National Institute for Health and Care Excellence
NPT	normalisation process theory
PPE	personal protective equipment
PPI	patient and public involvement
QoL	quality of life
QPR	questionnaire on the process of recovery
RA	research assistant
RCT	randomised controlled trial
RfPB	Research for Patient Benefit
SAEs	serious adverse events
SAP	statistical analysis plan
sEIP	standardised Early Intervention in Psychosis service
TS	treatment satisfaction
VC	virtual consultations
VLOG	video log

Plain language summary

Around 7500 young people in England develop psychosis every year. Early intervention can improve long-term outcomes but 25% of young people drop out of services each year. The study aimed to find out if the Early Youth Engagement-2 approach would increase the time people stayed with the service and improve mental health outcomes. The Early Youth Engagement-2 approach includes a website, booklets and other resources to support young people and families; and a training programme for staff on how to work using 'motivational' techniques and social approaches.

The study compared two groups, one who received the Early Youth Engagement-2 approach and another who received standard support across five sites. A total of 1027 people between 14 and 35 experiencing their first episode of psychosis were included in the study.

We found no differences between the two groups for drop-out, service use or mental health outcomes, but we did find that the number of young people who disengaged was much lower than expected based on previous research. Possible reasons for the lack of difference between the groups included better-quality teams, short follow-up times, strict definitions of drop-out and first-episode psychosis, high staff turnover, COVID-19 and the way data were collected. It is also possible that more targeted use, instead of a whole team approach, might have better outcomes.

While our cost-effectiveness analysis carried some uncertainty, our best estimates showed that in 1027 people, the Early Youth Engagement-2 approach lowered the overall mental healthcare cost, on average, without detriment to mental health outcome, due to lower unplanned nights in hospital, crisis and Mental Health Act contacts. We had a small sample of 232 people for our analysis of wider social outcomes, so we must be very cautious about these results, but they showed some evidence that Early Youth Engagement-2 was linked to more days in education, training, employment and stable accommodation.

Scientific summary

Background

Psychosis is a potentially devastating condition affecting 1–2% of the population, impacting mental health, quality of life and life expectancy. Early Intervention in Psychosis (EIP) services are pro-active, person-centred mental health services offering early detection and treatment in the critical first 3 years of illness. These services improve outcomes for young people, but 25% are reported to disengage within the first 12 months, at potentially substantial cost to their health and well-being. Our pilot work shed light on the barriers and facilitators to engagement in first-episode psychosis [FEP; Early Youth Engagement (EYE) study] and informed the development of a team-based, motivational engagement intervention (EYE-2) to improve engagement in EIP services.

Objectives

The main objectives for the EYE-2 study were:

1. To develop and refine an implementation toolkit (resources and training) for national roll-out; drawing on a normalisation process theory (NPT) framework and knowledge obtained from an implementation study in the original Sussex site.
2. To adapt the booklets, website and training to the needs of the diverse population of EIP service users; and to ensure they were up to date and tailored to local service variation, incorporating information from the ethnicity and lesbian, gay, bisexual, transgender and queer or questioning (LGBTQ) minority study.
3. To evaluate the effectiveness of the EYE-2 intervention with respect to the primary outcome: time to disengagement (in days from date of allocation to care co-ordinator to date of last contact following either refusal to engage with EIP or lack of response to EIP contact for 3 consecutive months); and secondary outcomes [Health of the Nation Outcome Scales (HoNOS), questionnaire on the process of recovery (QPR), DIALOG, service use] derived from routine service data at 0, 6, 12, 18 and 24 months post entry into the study, defined as date of allocation to an EIP care co-ordinator
4. To quantify the impact of the EYE-2 intervention on NHS mental health care, wider societal care system costs, clinical and social outcomes over a 12-month period; to evaluate the cost-effectiveness of the intervention; and to investigate the potential resource implications of the intervention for NHS mental health commissioners.
5. To develop and test a framework for implementation through a large-scale process evaluation using (1) NPT and (2) logic models, and incorporating all clinicians involved in EYE-2 intervention delivery.
6. To disseminate widely through the study website, peer-reviewed papers, service user publications and conference presentations.

Methods

Patient and public involvement (PPI) was integral throughout the project and used a multilevel team approach led by the McPin Foundation, with a PPI lead and a Lived Experience Advisory Panel at each site. The PPI team collaborated and led on aspects of design, training, delivery, evaluation and dissemination.

To address objective 1, we conducted 15 interviews with clinicians in Sussex, from all teams and disciplines involved in delivery of the original EYE intervention, using a topic guide informed by NPT to explore intervention processes, implementation processes and contextual barriers and facilitators. Data were analysed thematically, mapped onto NPT processes and used to refine the toolkit and develop the logic models.

To address objective 2, we interviewed 21 young FEP service users purposively sampled to reflect the main ethnic and LGBTQ profiles, and variations in spirituality, in 3 inner-city sites: London (n = 8), Southampton (n = 7), Manchester

(*n* = 6). The topic guide was co-produced with PPI and informed by the Cultural Adaptation Framework (CAF). Participants had access to the original EYE booklets and website link for 2 weeks prior to interview. Data were analysed thematically, mapped onto the four domains of the CAF and used to adapt the training and resources.

To address objective 3, we conducted a parallel-group pragmatic randomised controlled trial: 20 EIP teams (clusters) were randomised, stratified by site (London, Manchester, Thames Valley, East Anglia and Hampshire), to deliver either the EYE-2 intervention plus the standardised EIP (sEIP) service (11 teams), or sEIP alone (9 teams). The primary outcome was time to disengagement. Ratings of disengagement were based on deidentified case note data, and double-rated, blind to team and study arm by a trained RA and clinician. Secondary mental health (HoNOS), recovery (QPR), quality of life (DIALOG), death and service outcomes were evaluated using routinely collected NHS-England-mandated outcomes and case note data.

A pre-study power calculation confirmed that 90% power to detect a difference in disengagement at 12 months from 25% to 15%, would be achieved with 20 teams and 950 participants identified over a 12-month period, with an additional 12-month follow-up, allowing for 10% loss to follow-up per year. In the event, a total of 1027 participants identified over 14 months (with an additional 12-month follow-up) took part in the trial. The sample comprised *all* new FEP service users aged 14–35 who were allocated to a care co-ordinator during the identification period.

To address objective 4, case note data were screened by research assistants (RAs) to record all mental health service use over a 12-month period following allocation to care co-ordinator. Interview data on wider (societal) service use and social outcomes were collected retrospectively at 12 months, by RAs blind to study arm, from all consenting participants, using an adapted adult service use schedule. Costs were derived from national reference costs and tariffs. Intervention costs were calculated for training delivery, website and resource production and printing. The mental health clustering tool was used to derive likely future cluster in terms of low, moderate or high cost, and a cost-effectiveness analysis determined whether the EYE-2 intervention was dominant in terms of cost and/or outcome.

To address objective 5, a mixed-methods longitudinal process evaluation was conducted with all clinicians involved in delivering the EIP or the EYE-2 intervention, informed by the logic models and NPT and comprising the training evaluation (*n* = 197 for EYE-2 training and *n* = 282 for data collection training), a qualitative study of routine service delivery with 1 clinician in each EIP team (*n* = 20), a longitudinal qualitative study of experiences of EYE-2 delivery with 32 clinicians interviewed early (*n* = 11), mid (*n* = 10) and late (*n* = 11) intervention and a longitudinal quantitative study at the same 3 time points incorporating standardised and bespoke questionnaires (*n* = 70; *n* = 81; *n* = 68).

Results

The PPI team co-delivered the EYE-2 training, refined and delivered the intervention social groups and co-developed the evaluation tools. The implementation study revealed 13 themes relating to lasting impressions of the EYE intervention, implementation processes and barriers. Organisational support was deemed important; and resources, patient and staff characteristics, such as patient literacy, staff caseload and the need for memory prompts and booster training could impact implementation. Adaptations to the resources and toolkit were proposed and incorporated. The process-oriented logic model identified three core and interacting mechanisms of change: (1) the use of the social network as systemic support to identify and achieve goals; (2) an enhanced therapeutic alliance and motivation to achieve goals; and (3) the use of the resources as a psychoeducational tool to facilitate goals and treatment choices. It was anticipated that use of these approaches would improve engagement and outcomes.

The ethnic and LGBTQ diversity study identified seven cultural factors with the potential to impact on engagement. In terms of philosophical orientation, there was a need to consider differing cognitions and beliefs between staff, service users, family members and spiritual leads; to consider the multiple intersecting facets of culture, and the role of faith-based support. Language was a barrier to engagement, especially for families, and use of interpreters raised confidentiality concerns. Practically, service users described stigma and discrimination relating to mental ill-health, LGBTQ and ethnic minority status. For some families, mental illness was a taboo topic, and some LGBTQ service users described their sexuality as invisible in services. Adaptations were made to the resources and training. Booklets

were translated into 12 languages. There was hope that the resources could open up topics for discussion. In terms of technical adjustments, it was critical for those from diverse backgrounds to increase trust in the therapeutic alliance, and in terms of theoretical modification, the adaptation of therapeutic approaches to individual differences was crucial.

The trial revealed that baseline characteristics were well-balanced across the intervention (n = 652), and sEIP (n = 375) arms: 21% of participants were lost to follow-up, and of these 60% moved out of area, or abroad. Data from participants lost to follow-up were censored, so primary outcome data were available for the entire sample. Disengagement rates were very similar across the intervention and sEIP arms (16% vs. 15.7%). Multivariable Cox regression on 1005 participants, adjusting for site, age and substance use at baseline, estimated an adjusted hazard ratio (95% CI) for EYE-2 + sEIP to sEIP alone of 1.07. This indicates the observed hazard of disengagement was slightly higher in the EYE-2 + sEIP arm though, within limits of 95% confidence we estimated the hazard ratio to be between 0.76 and 1.49, hence ruling out a reduction of more than 24% in the risk of disengagement in the intervention arm (p = 0.713). There were no differences between arms for any of the secondary outcome measures. Service users in both arms improved similarly in mental health, recovery and quality-of-life outcomes, and there were no differences in nights in hospital, accident and emergency visits, or Section 136 use. Although for those who did have an admission, median nights in hospital were marginally fewer for the intervention arm (27 vs. 33 nights). There were four deaths up to 12 months: one in EYE-2 and three in sEIP. The median number of National Institute for Health and Care Excellence guidelines received was five in each arm. Sensitivity and subgroup analyses suggested no effects of COVID-19 (based on baseline collected pre vs. post lockdown), substance use, symptom severity, ethnicity, or educational level on outcomes.

Possible explanations for the lack of differences between arms included: lower than expected rates of disengagement due to insufficient follow-up times; stringent disengagement definitions; stringent caseload acceptance criteria; improved quality services due to Access and Waiting Time Standards (AWTS) and data collection training, such that there was limited room for further improvement on the primary outcome, and issues with fidelity to the intervention which was impacted by COVID-19. For secondary outcomes, differential missing data for those who disengaged meant there was limited opportunity to capture an effect of the intervention after someone had disengaged, and the choice of secondary outcome measures, while presenting the best opportunity to collect data on people who were disengaging, may not have captured the most critical effects.

Health economic case note data were available for up to 945 (92%) of the sample and revealed a lower mean cost of mental healthcare utilisation, after accounting for intervention costs, in the intervention arm of −£788 (95% CI −£3571 to £1994) with a probability of 28.8% that the total mental health system costs would be higher for intervention. This reflected lower costs for unplanned admissions, crisis and Mental Health Act assessments. The cost-effectiveness analysis indicated a 43.4% probability that the EYE-2 intervention was dominant in overall cost reductions in the context of marginally better mental health states, compared to sEIP. Mean total societal cost was lower in the intervention arm −£526 per participant (−£7031 to £5980) with a probability of 43% that this would be higher in the intervention arm. Only 22% of the eligible sample consented to and completed the societal cost interview which indicated that the EYE-2 intervention was associated with 5.73 more days spent in stable, independent living (95% CI −1.79 to 13.25) with the probability of a positive outcome for the intervention of 98%; 7.56 more days spent in paid or unpaid employment (95% CI −35.64 to 50.76) with the probability of a positive outcome for the intervention of 77%; and 30 more days spent in education and training (95% CI 1.52 to 53.68) with the probability of a positive outcome for the intervention of 99%. Although these findings are consistent with key aims of the EYE-2 intervention and components of the manuals, training programme and resources had some margin for error when considering Cis and the analysis of wider care system costs and social outcomes must be viewed with particular caution as only 22% of the eligible study sample provided data.

The process evaluation revealed widespread disruption due to COVID-19 and impacts of AWTS on caseload such that only schizophrenia-spectrum cases were likely to be accepted. Implementation processes were highly heterogeneous and fluctuated over time, with both facilitators and barriers in operation and a constant pressure to adapt to the changing context. Two of the three mechanisms of change (systemic support and therapeutic alliance) were disrupted by COVID, and there was no effect of the intervention on therapeutic alliance. The most likely active mechanism for

change was via psychoeducational processes, as the EYE-2 resources were very well-received, used in structured ways, positively appraised and associated with stronger therapeutic alliance.

Limitations

Limitations include the high loss to follow-up, especially for secondary outcomes in those who disengaged, the smaller subsamples of clinician in the process evaluation and service users in the societal cost evaluation, the non-standard secondary data collection processes for HoNOS and the delivery of the engagement intervention during a global pandemic which impacted on implementation and outcomes.

Conclusion

In the primary analysis of clinical effectiveness, 95% confidence limits ruled out a reduction of any more than 24% in the risk of disengagement using the EYE-2 intervention. COVID-19 had a substantial impact on implementation of the EYE-2 intervention and fidelity to intervention delivery was low across multiple teams and time points. Access and Waiting Time Standards had a substantial impact on the quality of standard EIP service delivery during the trial, which likely impacted results. In a cost-effectiveness analysis, estimates fell in the direction of dominance of the EYE-2 intervention (reduced costs, better mental health states and social outcomes). The intervention was most likely delivered as a standardised psychoeducational tool. Clinically, this project is valuable, comprising the largest study to date, looking at engagement, mental health and EIP outcomes in a total population sample. Qualitative feedback suggests that the booklets, website and psychoeducation approach were highly valued by clinicians, service users and families, and together the resources and model for lead practitioners might support and standardise best practice in EIP. Future research should consider targeted engagement programmes focused on inpatient staff and FEP service users where there is substantial need, and psychoeducational and supported self-management programmes aimed at those wishing to enhance their social and vocational outcomes. More research is required regarding engagement with EIP services in the UK and on the impact of youth migration within the UK on their social isolation and mental health outcomes.

Study registration

This study is registered as ISRCTN 51629746.

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Chapter 1 Introduction

What is the problem being addressed?

In England, 1–2% of the population,[1] 7500 new young people each year,[2] develop psychosis. Psychosis has devastating consequences, with substantially poorer quality of life (QoL) and high disability-adjusted life-year losses.[3] People with psychosis die up to 25 years earlier than the general population,[4] including from suicide, usually within the first 3–5 years.[5,6] The first 2–3 years are pivotal in determining long-term trajectories.[7–12] Early Intervention in Psychosis (EIP) services are proactive, person-centred mental health services offering early detection and treatment in this critical 3-year period.[13–32] The recent Access and Waiting Time Standards (AWTS),[33] published by NHS England, requires all Clinical Commissioning Groups (CCGs) to ensure currently that at least 60% of all new emerging psychosis cases in England are engaged within 2 weeks with a National Institute for Health and Care Excellence (NICE) concordant EIP service. Yet treatment disengagement from services is high,[34–43] estimated previously at 30% of young people in a recent systematic review across all service types and follow-up periods,[34] and 25% within the first 12 months in standalone EIP services, including in our own pilot study.[35,36,44,45] This is a major problem. National policy, investment and service structure are focused on ensuring that young people are proactively engaged in assessment, and offered a full EIP care package to prevent them 'falling through the gaps', receiving inadequate care, poor outcomes and greater subsequent healthcare use (p. 27),[33] but one in four disengage. There is limited evidence for methods to promote engagement in the subsequent 3 years. Our work began to provide this evidence.[44–46] We now understand why people disengage and want to test the effectiveness and cost-effectiveness of a team-based motivational engagement intervention to reduce disengagement from EIP services. A large-scale process evaluation will provide knowledge and tailored resources to support health services to implement the intervention nationally.

EIP services improve health outcomes for young people with psychosis in the long term, but 25% of young people disengage in the first 12 months. Drawing on a successful Research for Patient Benefit (RfPB) funded feasibility and pilot study, we aimed to test the team-based motivational Early Youth Engagement (EYE) intervention to improve engagement and outcomes across ethnicity, service and geography.[47]

Why is the research important in improving the health of the public and/or patients and the National Health Service?

There is a clear health need: engagement with EIP services leads to increased service user satisfaction, fewer symptoms, relapses and hospital admissions, better health, well-being, social and occupational function and fewer suicides[12,48–52] in the medium to long term.[18–22,48] Disengagement of young people with psychosis represents a significant cost to their health and well-being and impacts on families, society and the NHS.

There is an expressed need from researchers and NHS management to focus on engagement, with some researchers suggesting it is the most important outcome of EIP services.[53] The College Centre for Quality Improvement made time to disengagement a recent EIP audit requirement.[54]

The Early Youth Engagement-2 (EYE-2) project has the capacity to generate new knowledge of how to effectively engage young people in EIP services.

There is sustained interest and intent to increase access to EIP services for people of all ages who develop a first episode of psychosis. AWTS are supported by NHS England, which committed to further access and engagement targets by 2020.[33] EIP service access is 'a clear national priority for the NHS' (Kendall[33]), and local NHS services were required to include EIP development in their immediate and long-term sustainability and transformation plans.[33] This development was supported by £40 million for staff and training, in 2015–6 alone and £70 million by 2020.[55] Yet disengagement from these services threatens the quality of health outcomes and nullifies this investment for 25% of young people.

The financial cost of psychosis to society, including health care, families, unemployment and death, is estimated at £11.8 billion per year.[56] EIP services demonstrate savings of 30–50% over standard care, over periods of at least 8 years;[57,58] £5000 per person per year based on days in hospital;[57] £7972 net savings per person after 4 years, £6870 in the next 4–10 years, £15 for every £1 spent on EIP services after 10 years.[59] Even with suboptimal engagement, EIP is estimated to result in £63 million of savings per year to society, £34 million of these to the NHS.[60] The potentially greater cost savings of full engagement are not yet known. A cost-effectiveness analysis will assess whether the intervention can be delivered with cost and quality benefits.

This study will also determine the service engagement needs of ethnically diverse populations, refining training and resources to ensure needs are met. We aimed to work closely with our commissioner, manager, NHS England collaborator and co-applicants, to ensure that learning derived from this project shapes our toolkit (manuals, resources, training and commissioning guide) to aid future service delivery and help to meet and inform future NHS targets.

The process evaluation across all EIP services will provide in-depth knowledge of organisational factors at a macro and micro level that influence implementation and integration with standard care pathways. This will facilitate national implementation leading to real change in NHS service delivery and care outcomes. An effective engagement intervention for young people in EIP services has the potential to improve mental health, occupational and social outcomes, reduce immediate and long-term financial and other burdens on the NHS, families and friends.

Why is this research needed?

Our recent RfPB grant[44,45] developed the EYE intervention, drawing on views of service users and their families of barriers and facilitators to engagement, and on initial literature that disengagement is linked to younger age, substance use, coping styles, family contact and knowledge of services.[34,37,38,42] A systematic review published near the start of the study identified 30% disengagement across all types of first-episode psychosis (FEP) services,[34] with 25% disengagement within 12 months from EIP services.[34–36,44,45] To date, only limited evidence from our own work has identified strategies to maintain engagement from initial assessment or when a young person begins to disengage.

Our Delphi consultation with clinicians and managers reached consensus on the EYE intervention and resources. Our pilot study found that service disengagement decreased from 24% prior to 14.5% post-EYE intervention. Qualitative feedback from service users, families and staff revealed improvements in personal recovery (social inclusion, hope, trust, practical goals) and engagement (communication, collaboration, family involvement). The use of anonymised data, collated and completed by research assistants (RAs) in EIP teams, was feasible. A longer training, detailed manual, intervention checklist and social group protocol aimed to enhance delivery. The RfPB Programme Director, Professor Armstrong 'commended EYE, as a good early study making headway in a difficult problem area and achieving all it set out to do'. The study met with approval from EIP Regional leads and NHS England, who quoted the study in their recent EIP policy guidelines.[33] The study is timely, as the new AWTS[33] aims to ensure that EIP services are the focus of sustained NHS attention, that standard EIP services are delivered according to clear guidelines, and that delivery and outcomes are measured routinely in a standard way. We next aimed to address this engagement evidence gap with a full trial.

Main objectives

1. Develop and refine an implementation toolkit (manuals, commissioning guide, implementation checklist) in the first 6 months of the project, and refine at the end of the trial for national roll-out; co-developed with the Sussex EIP clinical lead, manager and general practitioner (GP) commissioner, drawing on a normalisation process theory (NPT) framework and knowledge obtained from the implementation study in the original Sussex site.
2. Refine the booklets, website and training, based on NHS England guidance on health inequalities that communications should be 'appropriate and accessible to meet the needs of diverse [ethnic minority] communities' (p. 9[33]); contain current evidence; and are tailored to local service variation. This will be completed in the first 6 months of the project, and further refined at the end of the trial.

3. Evaluate the effectiveness of the intervention with respect to the primary (researcher collated) outcome: time to disengagement (in days from date of allocation to care co-ordinator to date of last contact following either refusal to engage with EIP or lack of response to EIP contact for 3 consecutive months);[36,41,61,62] and secondary routinely collected and researcher collected outcomes [Health of the Nation Outcome Scales (HoNOS), QPR, DIALOG, service use] that enable testing of hypotheses developed from the original EYE study, and derived from routine service data at 0, 6, 12, 18 and 24 months.
4. Develop and test a framework for implementation using (1) NPT to explore actions, context, process, structure, and coherence with standard care, including sense-making, effort, action, commitment, participation and reflection on progress; and (2) logic models to test variation in roles, responsibilities, beliefs, activities, relationships, processes, structures, affective and cognitive components, at an individual, social network, team and system level. And to complete a large-scale process evaluation incorporating all clinicians involved in EYE-2 intervention delivery, assessed through questionnaire at start, mid and end of trial, and qualitatively in interviews.
5. Determine societal and NHS costs, cumulative cost savings, health outcomes and overall cost-effectiveness of improved EIP engagement and produce a commissioning guide, with GP commissioner input.
6. Disseminate widely through the study website, peer-reviewed papers, service user publications and conference presentations.

Chapter 2 Patient and public involvement in the Early Youth Engagement-2 project

Aim

The aim of the patient and public involvement (PPI) in the EYE-2 study was to ensure that the voices of people experiencing their first episode of psychosis, and carers, were embedded in the implementation of the EYE-2 intervention across the sites included in the trial, and in how the trial was run. This chapter details the approach and outcomes of the PPI in EYE-2 and was written by the PPI co-applicant with input from the PPI leads using the GRIPP-2 guidelines.[63]

Methods

The EYE-2 study used a multilevel approach to PPI. Each of the five sites had a PPI lead who was an expert by experience, employed for between 0.5 and 1.5 days per week dependent on-site, at a band 5 (senior) level. This lead was embedded as part of the site's unblinded study and service teams. The PPI leads were supported by their site team and Rose Thompson and Tanya Mackay, Senior Research Managers at McPin.

Before the set-up of the EYE-2 PPI team, a Sussex-based PPI group of three service users and a local PPI lead provided input to develop the topic guide for the ethnicity study. This was then submitted for ethical review prior to the start of the project.

At the outset of the programme, the PPI leads were given training by Rose Thompson and Kathryn Greenwood that covered some general trial methodology, the specifics of the EYE-2 study, and their role within the project. We also discussed how lived experience could be incorporated into different work packages and how the PPI leads would be supported in their role through the project. The PPI leads were also provided with a collection of written resources from the study team in the form of an information pack about the study and trial methodology. The PPI leads were responsible for developing and leading the intervention social groups and convening regular Lived Experience Advisory Panels (LEAPs). They were also involved in randomised controlled trial (RCT) intervention training to teams involved in the trial and bespoke training for RAs. The PPI leads met as a group at least once per month [with additional meetings at the start of the Coronavirus-19 (COVID-19) pandemic to support study changes to accommodate lockdown regulations], with the meetings facilitated by the PPI co-applicant (RT/TM). The PPI leads were also involved in dissemination via video logs (VLOGs), written blogs, writing the lay summary, writing a booklet guide to setting up and running EYE-2 social groups and writing a paper on their work on a servicer user HoNOS[64] tool which will be submitted for peer review.

The social groups were held on average two times per month, and the PPI leads worked with the LEAP and service users who attended to develop these. Service users were involved in deciding activities and format in both in-person and online modes. The PPI leads supported several service users to start developing the confidence and skills to run these social groups. However, due to the impacts of COVID-19, the social groups required ongoing facilitation by the PPI lead. At one site, limited groups were held due to a recruitment freeze during the pandemic that prevented a PPI lead from being in post for delivery. The total number of social groups was made available to the whole caseload and attendance was as follows: Hampshire: 29 groups with 31 instances of attendance by an EYE-2 patient; Thames Valley: 109 groups with 93 instances of attendance by an EYE-2 patient; Norfolk: 33 groups with 12 attendances by an EYE-2 patient and Manchester: 57 groups with 63 attendances by an EYE-2 patient. London was an exception as there were 31 groups, but attendance was not reported separately for EIP and EYE-2 patients. There were 121 attendances in total of which approximately 50% (n = 60) were EYE-2 patients.

Lived Experience Advisory Panel meetings at each site were held regularly throughout the study, with online formats starting during the COVID-19 pandemic. Although the PPI leads built good relationships with local service users, these panels were often a mixed group of new and ongoing attendees. Positively, this did provide a wider range of voices and experiences; however, it also required the PPI leads to provide additional support at the start of each meeting to induct people into the group and explain the study and tasks. LEAP members were reimbursed for their time per their site's involvement payment policy. Like social groups, LEAP meetings were limited in one site due to the pandemic recruitment freeze. At least 1 LEAP meeting was held at each other site (2 meetings in London), between January 2020 and June 2021, incorporating 18 service users and 8 carers. There were also meetings prior to these dates, for which numbers were not recorded, and a website development workshop that included PPI leads and LEAP members.

The LEAPs were involved in a range of significant activities across the study, including website and material development, development of a telephone self-report HoNOS data collection tool, review and adjustment of the economic service user questionnaire (described in *Chapter 6*), redesign of outcomes reports for service users, review of focus group materials and the lay summary. All materials for activities were shared with LEAP members before meetings allowing time to prepare. This approach also facilitated access for people who felt more confident providing written input rather than in meeting input. All LEAP work was summarised by the PPI leads and sent to the Chief Investigator and Trial manager to inform study changes. At subsequent LEAP meetings, the PPI leads would update members on whether and how their input had been used and why and share any updated documents, ensuring good communication to the members.

Outcomes

Materials and website

At the outset of the study, the PPI team were involved in making choices around the design of the EYE-2 website and information booklets and worked with the design company to implement these. They were also involved in developing the content of advertising materials to be used in participating NHS sites that informed service users that their service was participating in the trial. Additionally, a consultation event on the website was held with PPI leads, LEAP members and clinicians from multiple sites; approximately 40 people attended. The LEAPs reviewed the information sheet and focus group questions for the Meaningful Change in questionnaire on the process of recovery (QPR)[65] and DIALOG[66] qualitative study. Again, they provided feedback on how these could be improved to ensure they were clear and accessible and advised the focus group leaders to ensure good engagement in the data collection. See *Appendix 1*, *Figures 22* and *23* for example website discussions and booklet additions.

Social groups

Social groups formed an important part of the intervention, allowing people to connect with peers with shared lived experience in a social environment. Activities were driven by the preferences of service users who joined the groups. The initial plan for the social groups was that they would be set up and facilitated by the PPI Leads, with service users taking over responsibility for running these over time. Several groups had begun to achieve this, with service users starting to feel more confident in running groups. However, when the COVID-19 pandemic began, all groups were moved to online formats in line with restrictions, and consequently, the PPI leads needed to continue their role in facilitating the groups. Notably, the PPI leads were able to use their own experience of overcoming mental health issues and share their stories, where it was appropriate and when they felt comfortable. This helped build a sense of optimism, shared identity and respect within the social groups. Having a lived experience facilitator enabled the modelling and mentoring around interpersonal skills, problem-solving and building social relationships while allowing members to interact and learn at their own pace in a safe and supportive environment.

Some sites achieved a group of regular members who built well-established social relationships over an extended period. Some of the outcomes shared by service users or observed by the PPI leads included members enjoyed the social aspect and the sense of belonging; members became more aware of social opportunities and activities, and they developed the confidence to take them up, and members improved their interpersonal and communication skills within the group. Several members also continued their friendships outside of the organised activity sessions. During the pandemic, we were told that the social groups were critical for some attendees to help them feel less isolated.

The PPI leads also co-produced a booklet (*Figure 1*) sharing the importance of lived experience in running these groups and their advice for running social groups online and in-person. This booklet has been made available to all sites to support the continuation of social groups.

Health of the Nation Outcome Scales data collection tool and health economic service use questionnaire

Using a co-production approach, the PPI leads and LEAP members worked on the HoNOS data collection tool to make it more person-centred and suitable for telephone use. This new tool was initially anticipated to be used to collect telephone data where service users had disengaged; however, due to the COVID-19 pandemic, it also became a tool for the RAs to collect data remotely, where care co-ordinators were unable to do this. The PPI team have drafted a paper for peer review to share this new version of the telephone self-report HoNOS tool. This paper focuses on the importance of service user and carer involvement and co-production of mental health assessment tools. It is anticipated that this paper will be submitted in August 2022 with the PPI leads as the lead authors.

The LEAPs also reviewed and gave feedback on the health economic service use questionnaire, providing feedback on adjustments to ensure the questions were accessible to service users.

Training

The PPI leads were involved across the study in delivering training. Initially, they worked alongside the Chief Investigator and Trial Manager to deliver the RCT intervention training, and following this, also booster sessions at sites as needed. The PPI team had a particular role in these training sessions around role modelling what good and poor communication or experiences with services may look like within the EYE-2 framework. In all but one site, the PPI lead facilitated LEAP members (service users and carers) to deliver a session on the local experience of service engagement. This was important in personalising the training to each site and team and provided valuable insights for intervention delivery. One example of this impact was in the Thames Valley site, where one service user talked about the value of meaningful activity to their recovery and another talked of the value of fishing in the countryside. Two new sections were added to the treatment choices booklets, which reviewed the evidence base for meaningful occupations and use of green space, and the relevant service users provided quotes to accompany the sections (see *Appendix 1*, *Figure 23*).

Patient and public involvement leads were also involved in training the RAs in using the data collection tools through role-play scenarios and feedback. The involvement of the LEAPs and PPI leads in this training helped to ensure that the intervention was delivered appropriately and that RAs developed their confidence in comprehensive, person-centred data collection.

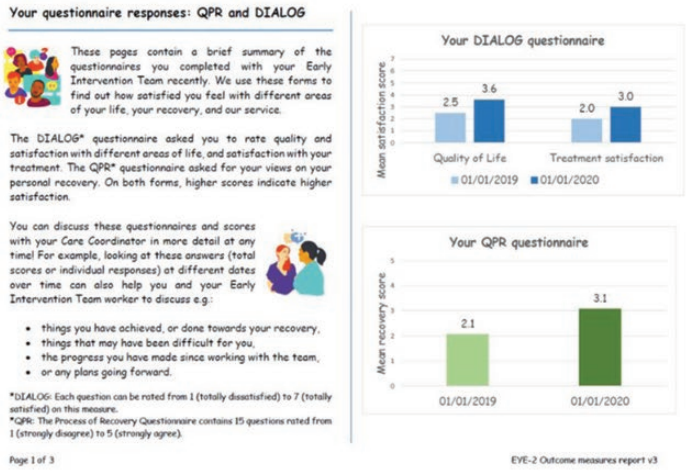

FIGURE 1 Example PPI-led social group booklet and outcomes report.

Outcome measures reports

The LEAP collaboratively reviewed and gave feedback on the Outcome Measures Report (see *Figure 1*). This feedback resulted in several changes, and the new Outcome Measures Report was reported to be more accessible and useful for service users.

Lay summary and dissemination

The PPI leads and LEAP have been involved in planning dissemination activities and co-wrote the lay summary for this report. Several PPI leads were also involved in writing blogs and filming video blogs on their work on PPI in the study (see *Appendix 1*, *Figure 24* and below):

https://mcpin.org/how-lived-experience-can-help-revamp-mental-health-tools/
https://mcpin.org/4-things-i-learnt-running-a-social-group-for-people-with-psychosis/

Discussion and conclusions

Overall, PPI has been integral to the delivery of the EYE-2 study. The multilevelled approach facilitated a diversity of voices across different aspects of the study and ensured that people with lived experience were actively involved in shaping the intervention, research design and implementation. This was particularly evidenced in the co-design of a new, person-centred version of the HoNOS, more suitable for remote use, which helped ensure the study could effectively continue data collection during the pandemic.

Having a PPI lead with lived experience at each site was a successful approach. It facilitated a more robust level of PPI across the study and intervention via the social groups. However, we did initially experience challenges with recruitment to these roles. At one site, due to limitations on recruitment during the pandemic, we were without a PPI lead for 8 months. Further, although the PPI leads worked to develop relationships with service users and carers locally, we found it difficult to retain regular LEAP membership. Although this meant we had a much greater diversity of people to inform the study, it did mean there was unanticipated work for the PPI lead in ensuring people were introduced the study to allow them to participate fully in LEAP meetings.

The social groups were a success, and the PPI leads successfully transitioned to online formats during the pandemic. Although the pandemic hindered service users from taking over the lead of these groups, we found that as the PPI leads had lived experience, this still allowed an environment where people felt safe and welcome. The production of the booklet accompanying this activity is also notable as it enables other Trusts to adopt a similar approach and was a piece of work that was led from a lived experience perspective.

Chapter 3 Objective 1: developing the intervention model and implementation toolkit

Objective 1 was to develop and refine an implementation toolkit and refine this as necessary at the end of the trial for national roll-out; drawing on a NPT framework and knowledge obtained from an implementation study in the original Sussex site. This chapter describes the development of the implementation toolkit.

Background

The Medical Research Council has long advocated the value of qualitative process evaluations, to aid understanding of how complex interventions work by producing a theory of change.[67] However, some have argued that this assumes that the intervention works in roughly the same way across all settings, whereas a truly complex intervention interacts with setting, context, those delivering and those receiving the intervention. In healthcare interventions, components may be strategically adapted to the NHS context, the skills of the clinician and the needs of the service user.[68,69]

A logic model is a conceptual framework, presented graphically, and used in a process evaluation to describe the relationships between components in a system and/or a theory of change.[70] The model can reduce some of the complexity by outlining the intervention components, and the interrelations between them. There is debate however, about whether such a model can truly capture the dynamic nature of intervention delivery.[71]

Mills *et al.*[72] categorised logic models according to whether they included context and whether or not they included the inter-relation between intervention components, suggesting that a model which includes both is rare but is most appropriate for understanding a complex intervention. They proposed that a more dynamic, context-sensitive model should be built up through rigorous qualitative evaluation to enable future scale up and implementation.

Rohwer *et al.*[73] distinguished between system-based and process-oriented models. A system-based model depicted the contextual framework in which the intervention was enacted, and incorporated participants, intervention, comparison, outcome, context and implementation in a static conceptual framework. The process-based model focused on intervention components and interactions between them, in a temporal causal pathway to outcome. These models could be developed prior to the start of the intervention, or iteratively, as the intervention progressed.

In the current project, we aimed to develop a system-based model that considered the intervention within its broader context, and a process-oriented model, that captured the interrelation between intervention components.

However, as noted by Mills *et al.*,[72] the complexity of an intervention is not always known until it is formally tested. The EYE intervention was tested in Sussex, but the resulting logic model was supplemented with additional feedback obtained from all participating teams in the national EYE-2 training programme. In this respect, both models were developed at least in part iteratively, but prior to the start of the intervention. The resulting logic models could then be used to develop a clearer conceptualisation of implementation and pathways to outcomes for the EYE-2 intervention, and to inform both the implementation pack (training, manuals and checklists), and subsequent process evaluation.

Aims

The current study had two key aims:

1. To utilise qualitative data collected during the original EYE study and data from the current implementation study collected 3 years after the end of the EYE study to develop logic models of the intervention context, components, relationships between them, and proposed causal pathway to outcomes.
2. To utilise these data to inform the development of the implementation toolkit including manuals, checklist and training programme for the delivery of the EYE-2 intervention.

Method

Participants

The study aimed to recruit 12–16 clinicians in Sussex who had taken part in the original EYE project, ensuring representation from all 6 teams and geographical locations (East Sussex, West Sussex and Brighton and Hove).

Procedure

All eligible participants were identified in discussion with the service manager and invited to take part. Consenting clinicians were then interviewed by a RA using a topic guide. The interview was audio-recorded and transcribed for analysis.

Topic guide

The topic guide (see *Appendix 2*) was shaped by NPT,[74] and designed to capture intervention components and processes, implementation processes, contextual barriers and facilitators.

Analysis

An inductive thematic analysis was applied to the transcribed data.[75] This method was selected as the study was underpinned by a critical realist perspective that reality exists, but knowledge is socially constructed, and there may be multiple differing but valid accounts of the same phenomenon. Multiple coding, triangulation and consensus discussions between the RAs, research lead, EIP lead and implementation lead were thus applied to agree on core themes.

Outcomes

Outcomes were organised into themes relating to (1) the nature and components of the intervention, (2) processes supporting implementation and (3) adaptations needed to the resources and implementation tool kit. The learning was incorporated into the final logic models, training and toolkit.

The development of logic models

The process for developing the logic model was iterative. Data from the initial qualitative study with service users, young people and families in the original EYE project developed the components of the intervention. Data from the second qualitative evaluation of the resulting EYE intervention with service users, carers and clinicians, refined the intervention components, and provided preliminary information regarding mechanisms of action. The current EYE-2 implementation study investigated key components and potential pathways to change, as well as context and system-based barriers and facilitators to implementation. Finally, the EYE-2 training consultation elicited further information relating to service and context that may impact on implementation and outcome. This feedback was collected informally: the draft logic model was shared and staff were encouraged to discuss additional factors that should be included. Feedback was documented by the RAs and included in the models as appropriate.

Results

Recruitment and demographics

Twenty-three clinicians (10 in West Sussex, 7 in East Sussex and 6 in Brighton) who were involved in the original EYE project between 2011 and 2015 and were still in post were invited to be interviewed. Of these, 8 clinicians did not respond in sufficient time to be considered for participation, and 15 took part in the final interviews (3 in Brighton, 5 in East Sussex and 7 in West Sussex). Specific demographic details are not provided to preserve anonymity. Seven participants were male and eight were female, they encompassed a range of ages, and disciplines included nursing, occupational therapy, social work and psychology, as well as team leader roles.

Results of the thematic analysis

The analysis revealed 13 overarching themes or domains (numbered 1–13 in bold below), which were summarised as appropriate in relation to the core NPT implementation processes of coherence, cognitive participation, collective action and reflexive monitoring. Importantly for the implementation of the EYE-2 intervention, interviews conducted

3 years after the end of the EYE project in Sussex revealed lasting impressions of the nature of the intervention and showed that staff still used key elements of the intervention.

(1) *Lasting impressions of the nature of the intervention – intervention components and interaction strategies*.

Ten specific subthemes were identified which summarised the nature of the EYE intervention from the Sussex clinician perspective:

The *procedures* involved in (1) *psychoeducation* and (2) *the importance of giving a physical resource* (booklets);

> S1: *'I'm trying to leave the young person with information after I'm gone so they've got a resource to look at when they're more chilled and in their own time, or with their family or friends. It's just about leaving them with something'.*
> S13: *'One of the chaps I gave it to, the next session I had I didn't get a chance to talk about anything I'd bought with me because he had read it and digested it and he had loads of different points he wanted to raise about it – so that's how I see it you know it's a really useful psychoeducational tool'.*

Enhanced *relationships* through (3) *the validation of the care co-ordinator therapeutic relationship as an intervention* and (4) *a focus on goals*.

> S4: *'To hear from service users that the development of that therapeutic relationship with a care coordinator is so valued by them, that's hugely satisfying for us . . . it provided my practitioners with a lot of affirmation, that engagement is an intervention in its own right. You don't always have to be offering, a treatment to young people. There's huge therapeutic value in developing a relationship with a young person who is experiencing psychosis'*
> S10: *'Service users wanted to have like goals that followed them to the next session as well'.*

Enhanced *communication* through (5) *providing collaborative treatment choices and plans*; (6) *offering shared language to reduce risk*; (7) *a motivational listening and reflecting approach* and (8) a *respectful language and communication style*.

> S6: *'It showed that we were open to any kind of treatment that might be helpful . . . I think maybe what the EYE project did was open up those conversations about alternatives to treatment'.*
> S1: *'It might be a prompt for someone to talk to us about something that they may not have been talking about before. Erm, particularly kind of around suicidal thoughts maybe, because that might be something that's more difficult for someone to share. They just don't want to tell you or don't know the language to tell you. And then here we go, it's all kind of written down for me. So, for a client to be able to be given a language to share that, I think, reduces risk'.*
> S10: *'Having somebody who listens to them and reflecting back to people you know all of that helps with their engagement . . . looking at the motivation for young people to engage with EI'.*

(9) *making clear that we work early and assertively with families* and (10) achieving expected *recovery outcomes including hope, resilience and self-management*.

> S10: *'It's hopeful. It's talking about treatment and the things that we provide and being very clear about how this can really help people in their recovery'.*
> S6: *'We were talking about this at our away day. Some of the stuff in the EYE booklets does promote resilience for the service user. It does support them to look after themselves and not have to rely so much on [us]'.*

These lasting impressions of the intervention are consistent with the original EYE intervention components and potential mechanisms of action and with the planned EYE-2 intervention incorporating (1) transparent, open, honest communication; (2) social network involvement; (3) collaboration and choice regarding difficult treatment issues and risk; (4) mental health staff, knowledge and support for meaningful goals; and (5) reducing personal barriers.[47] Greater emphasis was placed on psychoeducation as a process of change, and perhaps less on harnessing of the supportive social network.

The final Early Youth Engagement-2 process-oriented logic model including strategic intentions and components

Combining all these findings together, the key intentions and components of the EYE-2 intervention are a *belief* in promoting engagement and mental health recovery, through (1) enhancing *relationships* through active listening, supporting young people with their own goals and (2) *communication processes* of being honest, open and collaborative, and providing choices in the context of risk. Components of the intervention comprise (1) motivational and goal-focused *processes* to promote engagement, (2) social network *processes* aimed at harnessing *relational* support for enacting treatment goals and choices and (3) psychoeducation *procedures*, delivered largely through care co-ordinator *roles*, and utilising the EYE-2 *resources (objects)* including the website and booklets in systematic ways to achieve desired outcomes. The extent to which these components are implemented is expected to affect outcomes. An important point to consider in the process evaluation will be the extent to which each of the three core component mechanisms of the intervention are enacted to achieve change. An outline of the process-oriented logic model is provided in *Figure 2*.

Support for implementation

Coherence was demonstrated through **(2)** *the value* and **(3)** *positive emotional impact for clinicians*, **(4)** *the importance of service user involvement* and **(5)** *the compatibility with the EIP approach*. Clinicians valued the booklets and website which clearly incorporated service user voices and were trusted, evidence-based, user-friendly, professional, comprehensive, holistic and promoted understanding and broader perspective for service users, families and new clinicians. The booklets were used regularly, because they were glossy, accessible, informative, non-medical, non-threatening, hopeful and normalising, providing a reference and supporting introductions and engagement. They used everyday language put together by young people and helped service users to feel less isolated. They were thought to make clinical roles easier, save time and reduce workload. Staff particularly liked that all the information was 'at their fingertips' and they valued the 'act of giving' the booklets to their service users. The information, resources, videos, stories and moderated forum on the website were all thought to be helpful, especially when there was a desire to share information electronically, and the training was valued for initiating hope, excitement, reflection and a focus on the care co-ordinator/lead practitioner relationship. Positive emotional impacts for clinicians included happiness, pride, hope, excitement, vibrancy and motivation, while service users and carers were thought to feel reassured, comforted, contained, empowered and

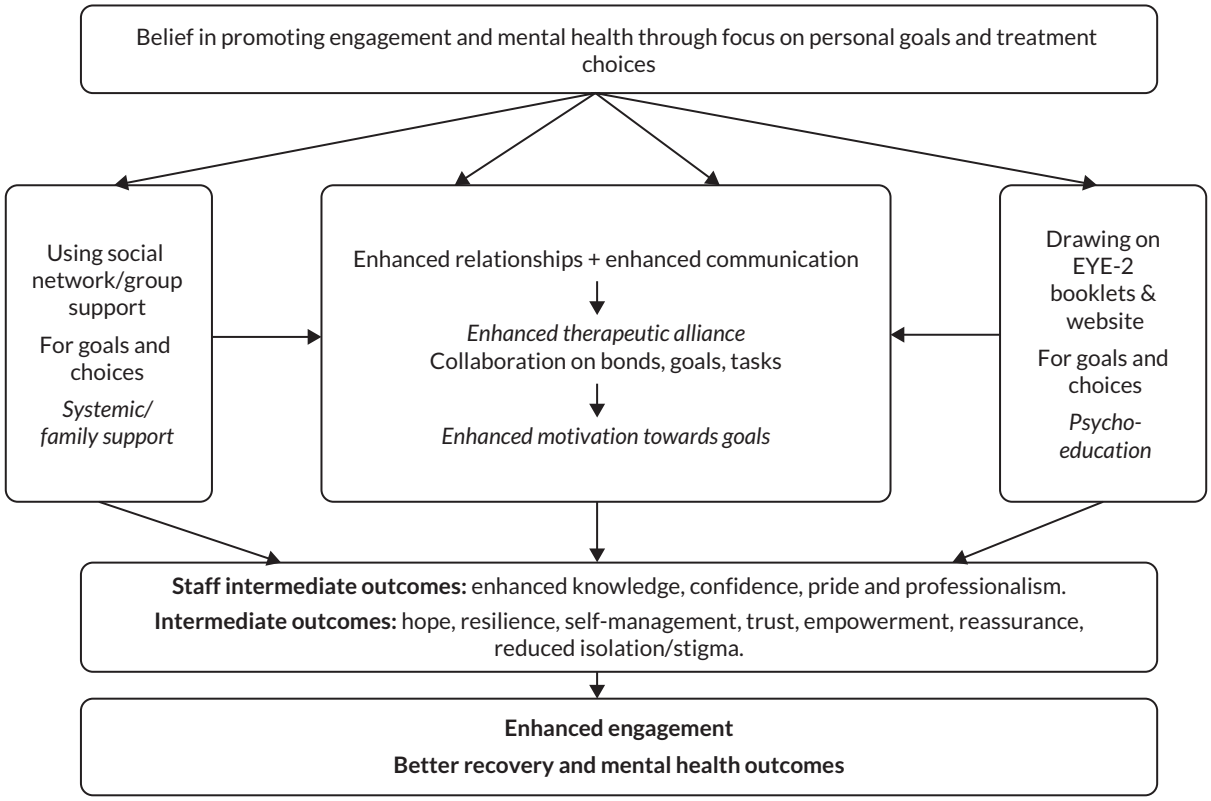

FIGURE 2 The EYE-2 process-oriented logic model.

less worried, anxious and bleak. The EYE approach and resources were seen as compatible with a good EIP approach and provided details regarding how to engage people. The booklets reiterated and endorsed what clinicians said verbally and offered a succinct package of what EIP offered. Service user involvement and the resulting impact on language and design helped to connect with new service users who valued the service user experiences and quotes.

> S7: *'I just think it helps us as a service to come over more sort of professional and I think people like it. I think it just adds maybe a bit more value to us . . . I think people remember to take the booklets because they look good and people value what's in them. You get a bit proud putting them out'.*
> S1: *'It's about being inclusive, collaborative, not using jargon. Providing as much relevant information as we can for people at the right time, at the right pitch, the right tempo. It definitely fits with the EI ethos'.*
> S1: *'The EYE project is a perfect fit for our style of working, our ethos, our approach, our values. The goals are the same: remove barriers to engagement, encourage positive meaningful engagement, encourage collaboration, bust stigma and myths around mental health problems'.*

Cognitive participation was in evidence in **(6)** *informal handovers to new staff and service users* who were inducted into the approach and in the **(7)** legitimisation of the approach through the *feedback from other staff, service users and families* such that staff were confident that the approach worked. The service user involvement impacted on the language and design of the approach, and further instilled confidence. Activation in terms of continued support for the intervention was evidenced across the interviews in the delivery of the intervention.

> S1: *'When new staff are inducted, these are the contents of the assessment pack, and the EYE project leaflets are part of it. My expectation would be that new members of staff take the time to ready through them briefly before they start handing them out'.*
> S8: *'We like using them. We use them regularly and we've got feedback from young people and their families that they're helpful'.*

Collective action was in evidence in the **(8)** *staff confidence*, which was critical to ensure the approach was used. Reading the materials boosted confidence, but conversely not reading the resources meant staff were less likely to use them. Lack of confidence in technology meant they were less likely to use the website, and some staff asked for flow charts of what to use and when. **(9)** *Ways of using the resources* were described such as using the resources as an introduction and a starting point, at assessment or sending materials out with the first care plan, using them flexibly dependent on illness phase, as a reminder and to reinforce key messages, in reviews and as a checklist for what's been offered, to educate other professionals about EIP, and in a structured way with friends. Collective action was further emphasised in how the work was allocated, with **(10)** *different staff engaging in different ways:* administration staff engaged as the first point of contact, care co-ordinators engaged holistically, but other disciplines used the resources to focus on their specific aspect of the work, for example nurses focused on physical health, support workers on activities and psychiatrists on medications. Appraisal or reflexive monitoring was at the individual level obtained through *positive staff, patient and service user feedback* which meant that clinicians were confident that it worked.

> S15: *'It was a routine part of our assessment pack. We would hand it out at that particular point routinely . . . or maybe send it out with a first care plan'.*
> S7: *'It's not just about what we offer it's about what we maybe have already offered, and people have turned down. It could just be a gentle prompt to allow families to know we've tried'.*
> S12: *'If a parent or a service user has contacted me with questions about different medications and what other things they can try. I'll often send them the treatment choices booklet and a reference to certain pages that I think are going to be helpful'.*
> S4: *'I think it's helped boost confidence in the way that we approach the work'.*
> S13: *'We all work differently but we all work equally hard in engagement'.*

The need for organisational support and contextual integration

In terms of **(11)** *organisation support* needed for implementation, there was reference to the need for booster training or 6-monthly refreshers, recaps and updates on principles, and induction training for new staff, to maintain the philosophy as the project had finished over 3 years previously. However, most support needs to be focused on contextual

integration and organisational support *within the teams*. Shared knowledge and strong leadership were viewed as important. There was a need for clinical and managerial support, discussions in supervision, reminders in team meetings and having the resources available. Memory prompts were also thought to be valuable including checklists, self-prompts, visible reminders and team champions who could help to embed the approach and remind staff when they were busy.

> S3: *'The service manager and the clinical lead, and the people in lead roles in EI. They all supported it and made it happen'.*
> S14: *'Leaders in the service having awareness and having it as part of their general agenda that there's a resource, don't forget about it, it has its use for X, Y, Z'.*
> S7: *'Clinicians in the team have talked about this before but, developing a checklist'.*

Incompatibility and barriers to implementation

A number of barriers were raised in terms of **(12)** *Incompatibility of EYE-2 with EIP*, or obstacles to delivery. These included

(1) Patient characteristics and processes such as mental state and risk, motivation and readiness, stigma and confidentiality. Staff were less likely to use the approach and resources if service users were agitated, in crisis, had low insight or had an at-risk mental state. Motivation and readiness of the service user were thought to impact progress. Stigma and issues of confidentiality were barriers to engaging both service users and their friends.
(2) Staff characteristics and turnover meant that staff were less likely to use approaches if they themselves were stressed, 'fire-fighting' or managing crises, had insufficient time to engage, or if staff turnover was high, leading to staff shortages. Staffing challenges contributed to a more medical focus, and staff turnover made it harder to keep up key messages.
(3) Resource characteristics meant that sometimes the booklets were seen as too much written information in one go.

> S15: *'Sometimes we have clients with a fairly fragile engagement, with quite poor insight who almost take exception to the idea that they have a mental illness. We have to tread very carefully and be very subtle and discreet in those circumstances'.*
> S2: *'My experience is that the more firefighting people are doing then the less things are gonna be used. Like the materials for instance, would be used less if people were going from crisis to crisis'.*
> S6: *'If somebody's concentration was so poor then written information, sometimes, they can't handle it'.*

Developing and refining the implementation toolkit

Finally **(13)** *specific recommendations for adaptations* were made regarding the implementation toolkit. In relation to the booklets, staff were concerned about raising hope for treatments that were not available in their teams and wanted some consideration of this in the booklets. They wanted more information on physical health, more information in other languages, and a changed design so that booklets were more visually distinct. Regarding the website, staff requested that specific information about EIP teams be included and noted that clinicians needed a 'reason' to visit the website. They thought that the website should be made easier to navigate and accessible on their phones. Staff also requested an implementation manual.

Staff training consultation on contextual influences

Additional informal data about service context that might affect implementation were gathered during the EYE-2 training programme from teams involved in the intervention delivery. Contextual factors expected to impact on EYE-2 intervention delivery included the nature of regional support for policy implementation (including outcome data collection), funding and staffing levels, care co-ordinator caseloads, availability of NICE-informed interventions and information technology (IT) equipment, office space and bookable group rooms. Geographical differences were expected to have an impact, including resource differences from North to South of England, and challenges for rural versus urban locations, in terms of travel and transport. Team differences expected to have an impact included team culture, ethos and enthusiasm; team inclusion criteria and discharge policies; staff turnover and sickness. Variations existed in staff and service user culture, spirituality and ethnicity, as well as variations in patient literacy, first language, spoken English, immigration status and sexuality. Variations in the way care co-ordinators introduced the project, and concerns about confidentiality and data security were also expected to impact on delivery and outcome.

Strengths and limitations

Strengths of this study lay in the ability to recruit clinicians who were still in posts in EIP services several years after the end of the previous EYE project in Sussex. This enabled us to access a unique insight into what was retained of the intervention approach and why, and what we should include to further support implementation. However, in some cases, the time elapsed since training meant that people had forgotten elements of the approach. In addition, those who had moved out of EIP services and clinicians who did not initially respond to the invitation to participate may have held different, less positive perspectives on the intervention approach, which we may have missed.

Discussion

The implementation study provided valuable information to support and evaluate implementation.

Adaptations to the implementation toolkit

The booklet content was updated: booklets were recreated in distinct colours; imagery and wording were changed to be more appropriate for older service users; physical health sections were added; resources were made available in other languages; and an explanation about availability of interventions was included, with a star indicating each of the core NICE recommended interventions. The treatment choices booklet was seen as too big for some patients, so each treatment choice was made available separately on the website, enabling staff to create a 'bespoke' treatment pack for each service user. The website was redesigned to be more accessible, user friendly (see *Chapter 2*), mobile first (accessible by mobile phone) and new sections were added including a 'resources for clinicians' section, designed to encourage use by providing everything clinicians might need to support their role, 'at their fingertips'. The content of the resource section was expanded in consultation with clinical teams during the EYE-2 training. An EYE-2 implementation manual was developed, and sections were included in the manual and training regarding when and how to use the resources, how to support implementation, and the importance of organisational support (see *Project document 1: Implementation manual*, pp. 40–54). A plan was instigated to identify an EYE-2 champion within each team to support intervention delivery. Additional adaptations to support implementation included the provision of business cards with website links, implementation checklists (see *Project document 2*), template friends and family letters, and resources adapted for ethnic, religious, spiritual and cultural differences (see *Chapter 4*). An adapted social group model was co-produced and co-run by EIP service users that aimed to promote social inclusion, reduce stigma and promote well-being, self-confidence and empowerment, by enabling service users to give something back to support fellow service users (see *Chapter 2*).

The process-based logic model

The final process-based logic model (*Figure 2*) was informed by the five core themes identified as barriers and facilitators to engagement in the original EYE project [(1) open, honest, communication; (2) involvement of the broad social network; (3) the service response to complex issues such as medication and hospitalisation; (4) the actions, attitude and knowledge of staff in support of service users' own holistic life goals and (5) the patient's own personal barriers and the extent to which clinicians could promote trust]. The model was further refined based on the qualitative feedback obtained from the original EYE project, and the current implementation data on intervention components and their interactions. Consideration was also given to mechanisms of action through therapeutic alliance, systemic and motivational behaviour change and psychoeducation[76–81] Potential intermediate outcomes on the path to maintaining engagement based on these qualitative studies included increased hope, goal-focus, trust, collaboration and choice, reassurance and reduced isolation and stigma. Staff identified personal processes of enhanced knowledge, confidence, pride and professionalism.

The system-based logic model

As anticipated by Mills *et al.* 2019,[72] the implementation study did not capture the full complexity of intervention delivery across contexts, as the implementation study was based within Sussex. Therefore, the system-based logic model (*Figure 3*) was expanded following consultation with teams across the country during training for the delivery of the EYE-2 intervention. Key contextual influences derived from the system-based logic model, and expected to influence processes and outcomes included (1) implementation capacity: care co-ordinator caseload size and funding model; (2) implementation context: geographical location, patient first language and ethnicity, staff turnover, service

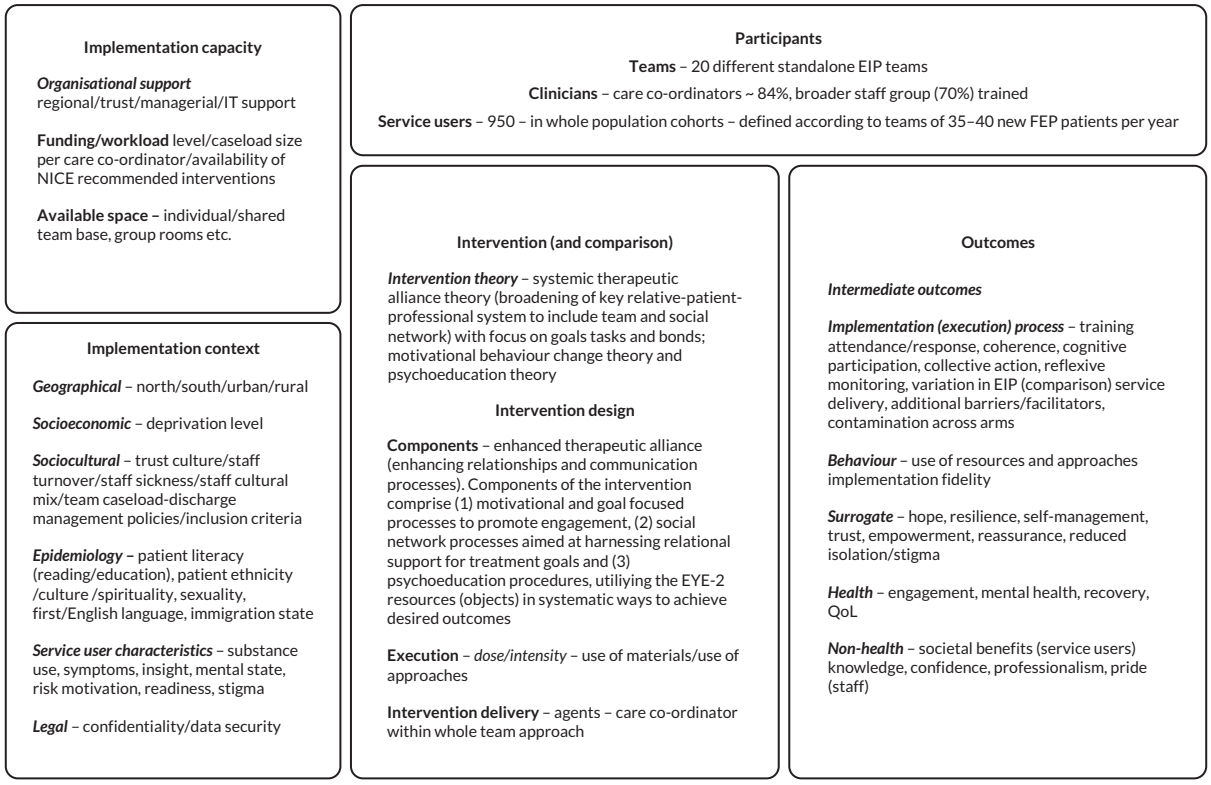

FIGURE 3 The EYE-2 system-based logic model.

caseload and discharge management policies, EIP intake criteria; and (3) implementation execution (coherence, cognitive participation, collective action and reflexive monitoring).

Conclusions

The implementation study enabled a closer specification of the intervention components, their interaction and potential change processes. Processes involved in supporting implementation and potential barriers were articulated at a patient, staff, service and context level. The findings were used to develop and refine the implementation toolkit and resources. In the effectiveness study, it is anticipated that randomisation stratified by site will balance some of the geographical, service, team and service user variations. However, implementation of a complex intervention interacts with context, influenced by those delivering and those receiving the intervention. Implementation will therefore be explored in detail in a large qualitative and quantitative process evaluation, informed by the process and system-based logic models and by NPT (see *Chapter 7*).

Chapter 4 Objective 2: applying the cultural adaptation framework to the Early Youth Engagement-2 approach to Early Intervention in Psychosis

The main objective was to refine the booklets, website and training, based on NHS England guidance on health inequalities that communications should be 'appropriate and accessible to meet the needs of diverse (ethnic minority) communities'; contain current evidence; and are tailored to local service variation. Adaptations will be based on an ethnicity and lesbian, gay, bisexual, transgender and queer or questioning (LGBTQ) minority study.

Introduction

Although the positive outcomes of EIP services are well documented,[82] high rates of disengagement from care are a concern.[53,83,84] Individuals from ethnic minority groups with FEP have poorer long-term mental health outcomes than their white British counterparts.[85] Various cultural and environmental factors can pose barriers to engagement and affect outcomes: two key factors are suspicion of services and coercive treatments.[86,87] Qualitative research with ethnic minority EIP populations has emphasised different competing models of mental illness, and the importance of spirituality, religion and faith institutions both as an initial path to help-seeking and for broader cultural and spiritual needs.[88,89] Interactions and interventions that are not culturally adapted may conflict with individuals' values and beliefs and lead to poor engagement.[47,86,90]

Engagement may also be lower in LGBTQ individuals with psychosis.[91] Many LGBTQ people report negative responses from staff including embarrassment, suspicion, condescension, ostracism and in some cases refusal of treatment[92,93] which can result in reluctance to seek support from mental health services.[94] There is need to understand and respond better to the needs of LGBTQ people requiring EIP services.

The Cultural Adaptation Framework (CAF) developed by Rathod and colleagues[95] aims to facilitate the adaptation of therapeutic approaches for diverse ethnic, spiritual and cultural backgrounds. The key principle of the framework is that every individual has a unique culture that reflects their life experiences and is influenced by their wider culture and subculture. This evidence-based framework has been evaluated through randomised trials[96–98] and used globally.[99] It is broad and flexible and therefore applicable to LGBTQ groups, and includes four core domains of adaptation:

Philosophical orientation: The worldview or life perspective differs for every individual, community and culture. These perspectives affect perceptions of health and illness, relationships with services and professionals, and treatment goals. Understanding an individual's philosophical orientation helps clinicians to engage with them.

Practical considerations: The relationship between religion, politics, culture, expression of sexuality, values and beliefs, and relationship with health services is complex in any community. Clinicians should understand this dynamic relationship and how employment, housing, justice and social care policies affect practical integration of individuals from diverse backgrounds, in order to provide holistic mental health services that supporting engagement.

Technical adjustments of methods and skills: Within diverse populations, the mode and manner of interactions or interventions, the setting, and the development of the therapeutic relationship may need to be modified to support engagement.

Theoretical modifications of concepts: Changes in the description of theoretical concepts may be needed to best fit the individual and their culture. This can involve different ways of explaining specialist concepts, with the use of appropriate metaphors.

We describe use of this evidence-based adaptation framework in the first phase of a large-scale multicentre trial – the EYE in FEP study (EYE-2) – to better understand the engagement experiences of individuals from diverse backgrounds and orientations and refine a series of mental health resources and engagement approaches to better meet the needs of various people experiencing FEP.

The Early Youth Engagement-2 study

Early Youth Engagement-2 is a cluster RCT comparing the EYE-2 intervention plus standardised EIP service to standardised EIP service alone, with randomisation at team level.[47] The intervention is a team-based motivational engagement intervention, delivered by EIP clinicians during their normal routine contacts. It is supported by a 2-day staff training programme and 6-monthly 'booster' training, and an implementation toolkit which comprises: (1) the implementation manual and checklist; (2) four myth-busting booklets on: mental health and help-seeking; Early Intervention services; treatment choices; and advice for family and friends; and (3) a companion website.

The intervention was developed by drawing on the views of services users and their families about barriers and facilitators to engagement, and on studies of factors associated with disengagement. The resources were developed in collaboration with young people, and include information, quotes and challenges to myths. EIP staff are encouraged to use the resources to enhance their engagement approaches with their service users (e.g. using booklets as soon as someone is taken on to caseload and in discussions of treatment choices, directing service users to information and resources on the website). Feedback from a feasibility-pilot study highlighted that the resources should more prominently consider the role of spiritual and cultural factors.

Aim

The aim of the current study was to explore the ethnic minority and LGBTQ service users' perspectives on the implementation toolkit resources used in the EYE-2 RCT. The CAF was modified to enable understanding of the requirements of ethnic minority and LGBTQ populations with respect to EYE-2 resources and training in the context of cultural, spiritual and sexual diversity.

Methods

Semi-structured interviews to allow qualitative evaluation of service users' perspectives on EYE-2 resources. The study was approved by the London-Dulwich Research Ethics Committee (REC reference: 18/LO/0362), and conducted in three EIP sites in England, chosen to capture the range of diversity in urban populations.

Participants

Participants were purposively sampled to reflect the main ethnic and LGBTQ profiles of the three sites, with 6–8 participants per site. The key *inclusion criteria* were consistent with the original entry criteria for the EYE-2 RCT: EIP service users aged 14–35 from ethnic and/or sexual minorities. The key *exclusion criteria* were an at-risk mental state, or not meeting FEP criteria as determined by each local service according to their own established criteria.

Procedure

Research assistants from each site received training in awareness of diversity based on the CAF.[100] This provided RAs with skills to engage with people from different minority populations to respect individuality, and to reduce inadvertent stereotyping.

Care co-ordinators identified potential participants who met the inclusion criteria and gained initial verbal consent. RAs then sent interested service users a participant information sheet, and a set of the original EYE resources (four booklets and the website URL), thereby providing sufficient material for discussion. An interview date was set at least 2 weeks later to enable time for participants to explore the materials.

Interviews were conducted face-to-face (F2F), with written informed consent. Interviewers used a topic guide that was developed in collaboration with a PPI group of ethnic minority EIP service users (see *Appendix 3*). In keeping with the CAF, questions explored culture, spirituality, ethnicity and sexuality, and how these affected service use and opinions of the EYE resources. Interviews lasted 45–60 minutes and were audio-recorded. Participants were reimbursed £20.

Analysis

Anonymised transcripts underwent thematic analysis.[75] An inductive approach was taken, whereby themes were identified initially through the coding of individual interviews, and then through comparisons within and then across the study sites.

In each site, a RA and a senior researcher independently coded the first interview and results were discussed to ensure a consistent approach to analysis. Cross-site meetings facilitated agreement between the three RA–researcher dyads on the process and the final theme structure. Themes were then mapped onto the CAF[100] (see *Appendix 3*, *Tables 30* and *31*).

Results

Table 1 outlines the demographic characteristics of the 21 participants recruited to the study. Ages ranged from 16 to 35 years [*M* = 25.4; standard deviation (SD) = 5.5]. Participants' ethnic and religious backgrounds were diverse: 16 reported a religious affiliation. Four reported non-heterosexual identities. As planned in the purposive sampling, the majority of participants at one site were from a LGBTQ background.

Seven key themes were identified across the four domains of the CAF (see *Appendix 3*, *Tables 30* and *31*). The first three themes – 'Differing Cognition and Beliefs', 'Multiple Facets of Culture', 'Language as a barrier' – addressed the framework domain of Philosophical Orientation. The themes 'Stigma and Discrimination' and 'Adaptations to EYE2 Resources' lay within the domain of 'Practical consideration'. The theme 'Trust in therapeutic alliance' was consistent with the framework domain 'Technical Adjustments of Methods and Skills' but also overlaps with other domains, and the theme 'Individual Differences' lay within the 'Theoretical Modifications of Concepts' domain.

Appendix 3, *Table 30* illustrates how many individuals identified with each theme. Most themes were present in most transcripts. The exceptions were 'Language as a barrier' which was only present for non-English-speaking participants or families, and 'Individual differences', which was found in fewer transcripts. *Appendix 3*, *Table 31* outlines the resulting adaptations made to the EYE-2 resources.

Domain 1: philosophical orientation

Theme 1: differing cognitions and beliefs

All participants reported the need for staff to be aware of diverse cultural and spiritual beliefs, and to understand different beliefs and attributions to mental health and how these influence engagement with treatment options. It was highlighted that sometimes it can be difficult to distinguish between religious/spiritual experiences and psychosis experiences, and that sometimes religious groups and clinicians may give different explanations of the same phenomena:

> *They were like praying, reading the Qur'an to me, taking me to the mosque. Although that helped a little bit, I think the medicine's more strong. My family pray. That is all they tell you to do . . .*
>
> *Participant 1*

In the next example, the respondent expresses how the religious community beliefs differed from their understanding, and that of mental health professionals:

> *Even at my church, I was still torn, because the church that I was going to were convinced that your healing came from Jesus and that medication, you shouldn't need it kind of thing, and you know I disagree. I disagree completely.*
>
> *Participant 21*

TABLE 1 Demographics of service users included in the ethnicity and LGBTQ study interviews

Site	Interviewee	Age	Gender	Ethnicity	Sexuality	Religion
London	*1*	20	Female	Black British	Heterosexual	Muslim
	2	20	Male	White and Black African	Heterosexual	Christian
	3	21	Female	Black British	Heterosexual	Christian
	4	22	Male	White and Black African	Heterosexual	Catholic
	5	23	Male	Black British	Heterosexual	Church of England
	6	28	Female	Black African	Heterosexual	Spiritual
	7	34	Male	Black African	Heterosexual	None
	8	35	Male	Black African	Heterosexual	None
	9	18	Female	Black British	Heterosexual	Christian
Hampshire	*10*	23	Male	Polish	Heterosexual	Atheist
	11	24	Female	British Asian	Heterosexual	Buddhist
	12	25	Female	White and Black British	Heterosexual	None
	13	26	Male	Black British	Heterosexual	Christian
	14	30	Male	White and Black British	Heterosexual	Spiritual
	15	31	Male	Asian	Heterosexual	Muslim
Manchester	*16*	16	Female	White and Black African	Pan-sexual	Wicca
	17	21	Male	British Asian	Heterosexual	Muslim
	18	26	Female	White and Black Caribbean	Lesbian	None
	19	26	Female	White	Lesbian	None
	20	29	Female	Black Caribbean	Lesbian	Christian
	21	35	Female	White and Chinese	Heterosexual	Christian

Theme 2: multiple facets of culture

Participants gave particular attention to different aspects of definitions of culture, and the links between culture, geography, spirituality, religion and sexuality. They noted that culture could be a mix of where they were from, where they lived, and what values they held. They stressed the importance of clinical team members understanding their culture as a whole, while also not making assumptions about their experiences based on their cultural background. Some participants reported that their parents' engagement with services was more influenced by culture than their own engagement: they noted that it would be particularly helpful to address different cultural and spiritual perspectives in the 'Friends and family' booklet.

The following quote illustrates one participant's experience of the intersectionality of different aspects of diversity:

> *Obviously like being LGBTQ and being mixed-race, like you're a minority in both, so obviously I am aware that I am a minority like, I don't, I don't know anybody else with psychosis regardless of gender or race, but I obviously am aware that it's probably a minority group within the mental health services.*
>
> *Participant 18*

Participants suggested that staff training should be provided on all cultures and religions and should encourage exploration of how culture affects their work.

Theme 3: language as a barrier to engagement

Several participants noted how language barriers affected both themselves and their family members when accessing services. Particularly, it was noted that the use of interpreters can affect confidentiality, especially when the language is a minority spoken language, meaning that there is a greater risk that the family already know or may become close to the interpreter. Making all the EYE-2 materials available in alternative languages was suggested as a way to help people with lower literacy in English. The following quotes illustrate language barriers to access to both mental health literature and mental health services:

> *I don't think my mum or dad would be uhh [pause] inclined to read it in English because . . . it's not their main language. Their main language is Cantonese, and I think if I had this in Cantonese, I would more likely read it or when they read it, they would more likely understand it . . . they didn't grow up in England and English wasn't their first language.*
>
> *Participant 11*

> *. . . yeah it is a big impact on accessing the service or even him talking to the service by himself so he has to go via someone else to speak what he needs to speak*
>
> *Participant 15*

Domain 2: practical considerations

Theme 4: stigma and discrimination

Participants spoke about specific stigmatisation of mental health difficulties. For example, some cultures and religions prevented individuals talking about their difficulties within their social networks: '[I]t's about confidentiality and they don't, if something happens like this, the person or the person's family whose going through it . . . they normally don't broadcast all these things' (Participant 15).

Stigma within families was also highlighted. Additionally, LGBTQ participants spoke about experiences of being stigmatised within health services and workplaces. It appeared that the relationship to mental illness may be exacerbated among ethnic minority and LGBTQ people:

> *Erm in terms of the community and mental health, there's obviously a high amount of people who have got mental health issues in our community because they've got discrimination to cover; they've got family members that completely don't understand; you've got religion; you've got so many things that could cause you to have mental health issues; environmental and physical problems that you'd have yourself anyway. A hell of a lot of battles to even think about, being gay, straight, or indifferent, and that's before you even start on who you're falling in love with or whatever.*
>
> *Participant 19*

Respondents described their difficulties in engaging with services and talking about their issues with family members. It was suggested that the resources could explore ways to open up conversations about mental health, for example, by including personal stories and quotes from service users of different backgrounds. Although some ethnic minority groups were concerned about being specifically represented in the booklets – in case this exacerbated stigma – LGBTQ participants felt invisible and wanted to see themselves represented. Participants also felt that services could facilitate conversations with family and friends if desired.

> *Fear of being sectioned, being judged for criminal activity, . . . Mental health is viewed as something dirty 'you're a nutter' and 'you're crazy' you are not a human. I don't feel confident in disclosing my mental health to anybody; I fear they will use it against me, like work. Nobody, not even this book can tell me that they won't be judgemental towards it. In my culture in Nigeria people thought mental health was madness . . . people would think I've had the devil inside me, that's what we kind of believe in my country. Something bad would happen to me, beat me.*
>
> *Participant 6*

> *It's kind of like the stigma that's around mental health, it's kind of broke it down for me cos I had a really difficult time telling people and speaking to my family, like it was over a year before I actually told anybody, so I relied quite heavily on Early Intervention cos I didn't really have additional support from friends and family for a long time*
>
> *Participant 18*

Theme 5: adaptations to Early Youth Engagement-2 resources

The general reaction to the resources was positive, although various barriers to access and use of the website and booklets were identified. It was highlighted that the original resources may not be representative of the broad audience of EIP service users, and that they should include more diverse images as exemplified by the following respondents:

> *I gave them to my mum, and she said there weren't any pictures of people of colour in there.*
>
> *Participant 13*

> *I feel like, it doesn't really include anything to do with religion. Obviously, it suggests that therapy, which is for mindfulness, which draws on Zen Buddhism, but it doesn't really include anything else or take into account people's religions. I don't know how you would include that in there, obviously it's quite a difficult thing to cover everybody's religion or take it into consideration, but I don't really feel there is much mention of it in there.*
>
> *Participant 18*

> *The younger generation they're more associated with phones and pictures and what the pictures look like, and the pictures speak more to them than what the words do . . . I've been back in work since I was pretty much discharged from the hospital and I can't see any pictures of work to like show me oh yeah people still work with mental health. . . yeah to have like a mixed range, to show like people in work, people outside of work and different cultures'.*
>
> *Participant 12*

However, it was also argued that focusing too much on one specific culture/religion may make some individuals feel targeted, stereotyped and less likely to use the resources. Concerns about stigma within the family unit and the visibility of EYE-2 booklets led some to suggest the potential benefits of being able to access the booklets online and being able to quickly hide website pages.

Participants proposed that staff should be trained to discuss differing beliefs to support individuals from minority backgrounds, and that there could be a section within the EYE-2 materials that explores how individuals may hold different views, and how these may vary from mainstream western views.

Example of adaptations of the resource toolkit are illustrated in *Figure 4* and *Appendix 3*, *Figure 25*.

Domain 3: 'technical adjustments of methods and skills'

Theme 6: trust in therapeutic alliance

Trust was regarded as critical for engagement, especially for people from minority backgrounds. Participants highlighted that previous experiences with services affect the level of trust they have for services in the future. Patient–practitioner relationships were an important topic, especially preferences for care co-ordinator characteristics. Some participants felt that having a care co-ordinator who shared a similar background to themselves (e.g. ethnicity, sexuality) would help to open up discussions:

> *Having a care coordinator or someone that was LGBT might have been helpful. I might have been more open to talking to them but obviously by the time my experiences, my symptoms of psychosis [started], I was like comfortable with my sexuality and stuff like that so it didn't really make a difference to me, whereas I think maybe with younger people, it might be, they might find someone more relatable if they're from the same kind of background as them.*
>
> *Participant 18*

However, others felt that the demographic characteristics of the care co-ordinator mattered less than their personality and the rapport they build.

> *I think the only thing that I would say is that, if the person has a preference, then they should be allowed to like make a choice. Like when . . . they were asking about my care coordinator, like, do you, want a male or female? And I-I said that I don't mind, so that wasn't really a bother for me, but for . . . other people it might be. So, I think it's about making sure they have like an option.*
>
> *Participant 16*

FIGURE 4 Revised and adapted EYE-2 booklets and website depicting ethnic and cultural diversity and multilingual content.

This difference of opinion suggests that a 'one-size-fits-all' approach is not appropriate, a finding also reflected in the final theme.

Domain 4: 'theoretical modifications of concepts'

Theme 7: individual differences in therapeutic preferences

Participants highlighted that individuals may understand and perceive the world in very different ways and that everyone's experiences are different. They suggested that staff could be offered support and training to be aware of individual differences, as well as diversity in individuals' preferences. Some participants stated that they preferred a more directive approach rather than the collaborative approach that is preferred in Western cultures. Being aware of individuals' preferences could be an important part of efforts to enhance engagement, as indicated in the following quote:

> *Erm just going over like what it is that they believe, because for different people . . . the belief means something different so . . . I just think that it's good to mention that in conversation when talking to services because it can be a reason for why they're feeling the way they're feeling . . .*
>
> *Participant 16*

Discussion

This qualitative study explored ethnic minority, and LGBTQ EIP services users' opinions of EYE-2 approaches and resources in the context of their treatment experiences. The seven core themes – differing cognition and beliefs; multiple facets of culture; language as a barrier; stigma and discrimination; adaptations to EYE-2 resources; trust in therapeutic alliance; and individual differences – mapped on to the four dimensions of the CAF: philosophical orientations; practical considerations; technical adjustments; theoretical modifications.[95]

The results further emphasised the importance of understanding the different cognitions, beliefs and models of illness held by service users and their families,[88] as well as the complexities of culture. The study highlighted intersectionality in the way in which stigma and discrimination arising from multiple causes can be additive.[92,93] Consistent with Rathod *et al.*'s[100] CAF, cultural factors influenced therapeutic alliances and preferences in EIP services. Language barriers had the potential to substantially impair how service users and their families engaged with services and EYE-2 resources. There is a clear need to make resources, services and research more accessible for those less competent in English language. However, there is also a need for broader cultural adaptation.

Adaptations to Early Youth Engagement-2 resources and training

The EYE-2 resources were evaluated positively, but several adaptations to the resources and the staff training were proposed and implemented. These are outlined below.

Across all resources, images were updated to depict greater ethnic and cultural diversity. Effort has been made to enable the EYE-2 website content to be translated into 12 of the most common languages as identified by the EIP teams involved in this project. Brief versions of the 'Early Intervention' and 'Friends and Family' booklets have been developed to include specific references to how EIP services aim to work with people spiritually and culturally: these have been translated into the same 12 languages. Information has also been included in the 'Friends and Family' booklet on issues such as religion, spirituality, cultural beliefs, immigration, confidentiality and use of interpreters, culture and mental health, and sexuality, and advice is provided that aims to reduce taboo, stigma and stress due to conflicting cultures and explanatory models of illness. The 'Treatment Choices' booklet now includes sections on faith-based support, including evidence for religion-focused cognitive–behavioural therapy (CBT). The 'Help-seeking and Mental Health' booklet now considers possible relationships between, and distinctions between, spirituality and psychosis.

The training programme for health professionals has been adapted to enhance service users' and family members' competence and confidence in talking about culture, religion and other diversities through personalised conversations.

Strengths and limitations

Few studies report on adaptations of proven interventions for use by culturally distinct populations.[101] EYE-2 is one of the few multicentre studies that incorporates this element from the outset. The National Institute for Health Research 'INCLUDE' initiative and ethnicity framework has also developed guidance to improve representation and address challenges to involvement of diverse populations in research.[102] The adaptations to EYE-2 resources and training address the four core questions posed by the framework, by (1) ensuring that EYE-2 can be more effectively applied to people from various ethnic and cultural backgrounds; (2) understanding how engagement with the intervention may differ for ethnic minority and LGBTQ service users and their families; and (3 and 4) reducing some of the barriers to engaging with the intervention.

A limitation of this study is the lack of representation of all members of the LGBTQ population – especially gay men. There is substantial research around mental health within LGBTQ populations; however, few studies have explored experiences of service use, particularly among people who have experienced psychosis.[91] This study highlights the need to explore further the experiences of FEP LGBTQ populations and their experiences of mental health services. Furthermore, the LGBTQ interviewees were recruited from the EIP services in an inner-city urban location with a large LGBTQ population.[103] These services may be more equipped to working with and supporting LGBTQ people. There would be value in exploring the opinions and experiences of LGBTQ service users living in areas without large, visible

LGBTQ populations. Purposive selection of ethnic, cultural, spiritual and LGBTQ diversity from three urban populations was a strength of the current study, but larger-scale work is needed to better understand each facet of diversity, as well as intersectionality between diversities.

Conclusion

To promote and facilitate engagement of service users and their families from different cultures and backgrounds, we should: include these individuals in the process of change and adaptations of interventions and approaches; produce materials in various languages; include everyday images of people from a range of ethnic minority and LGBTQ backgrounds; and include explanations of experiences and approaches to treatment from a variety of perspectives, in particular the voices of individuals with lived experiences from the ethnic minority communities. At the same time, we should work to reduce all sources of stigma, understand how multiple perspectives can be held simultaneously and used productively to support recovery, and respect cultural needs, while ensuring that we treat service users and family members as individuals.

Chapter 5 Objective 3: the Early Youth Engagement-2 cluster-randomised controlled trial effectiveness study

Introduction

Background and rationale

Early Intervention in Psychosis services improves health outcomes for young people with severe mental illness in the medium–long term, but 25% of young people disengage in the first 12 months at significant cost to their mental health, their families, society and the NHS. Our own feasibility-pilot work clarified the issues that affect engagement. This study aimed to test the new team-based motivational EYE-2 intervention to improve engagement and outcomes for young people. Full details of the trial are as detailed in the published trial protocol paper and the statistical analysis plan (SAP).[47,104] The SAP[104] was written following guidelines by Gamble *et al.*[105]

Study objectives

The main objective was to evaluate the effectiveness of the EYE-2 intervention with respect to the primary (researcher collated) outcome: time to disengagement (in days from date of allocation to care co-ordinator to date of last contact following either refusal to engage with EIP or lack of response to EIP contact for 3 consecutive months);[36,41,61,62] and secondary routinely collected and researcher collected outcomes (HoNOS,[64] QPR,[65] DIALOG,[66] service use) derived from routine service data at 0, 6, 12, 18 and 24 months post entry into the study, defined as date of allocation to an EIP care co-ordinator.

Hypotheses

The primary hypothesis was that, compared to standard EIP alone, the EYE-2 intervention would increase time to disengagement. The secondary hypotheses were that, compared to standardised EIP (sEIP) alone, the EYE-2 intervention would (1) improve mental and health outcomes; (2) improve recovery, social and occupational function, and satisfaction; (3) be moderated by effective implementation.

Study methods

Trial design

Early Youth Engagement-2 was a parallel-group cluster RCT, with clusters being the EIP clinical teams, with 1 : 1 allocation, stratified by site, to compare the EYE-2 motivational engagement intervention plus sEIP service to sEIP alone.

Setting

Participating services were EIP clinical teams (henceforth referred to as teams) in five geographical locations in England including East Anglia (four teams), Hampshire (four teams), Manchester (five teams), South London (three teams) and Thames Valley (four teams). These teams aimed to promote recovery and reduce treatment delay for people experiencing FEP by providing early access to multidisciplinary support and treatment. Participating teams were expected to have at least 35–40 new FEP cases per year meeting participant inclusion criteria.

Contamination

The cluster randomised design aimed to reduce the risk of contamination of sEIP teams with the EYE-2 intervention which is a team-based intervention, delivered largely by care co-ordinators (e.g. nurses, occupational therapists or social workers), but supported by all members of the team. In one site, two EIP clinical teams that were co-located were merged into one team for the purposes of the study to reduce the risk of contamination. A contamination protocol was developed and shared with staff in all teams, and contamination was monitored through the process evaluation.

Participants

Inclusion criteria for service users were: (1) consecutive referrals to EIP services during the study recruitment period from May 2019 to July 2020, (2) aged 14–35 years and (3) meeting criteria for a FEP as determined by each local service according to their own established criteria. Exclusion criteria were (1) subthreshold 'at risk mental state', not meeting FEP criteria, (2) referrals over the age of 35, (3) diagnostic uncertainty about psychosis 12 months post allocation to care co-ordinator and (4) service exclusion criteria such as organic or intoxication-induced psychosis and specific exclusions. Participants were followed up for 12–26 months.

Ethical issues

The trial received a favourable ethical opinion from London-Dulwich Research Ethics Committee (REC Reference: 18/LO/0362 IRAS: 238744), both centrally and locally at each site. No EIP participant consent was required for the main trial, which used only deidentified and routinely collected case notes and outcome data. Clinicians consented to take part in the intervention training and process evaluation.

The Early Youth Engagement-2 intervention

The EYE-2 intervention is described in detail in *Chapter 3* and *Figure 2*. The key intention was to promote engagement and mental health recovery, by (1) enhancing *relationships* through active listening, supporting young people with their own goals and (2) *communication processes* of being honest, open and collaborative, and providing choices in the context of risk. Components of the intervention comprised (1) therapeutic motivational and goal-focused *processes* to promote engagement (motivational therapeutic alliance), (2) social network *processes* aimed at harnessing *relational* support for enacting treatment goals and choices (systemic support) and (3) (psychoeducation) *procedures*, utilising the EYE-2 *resources (objects)* including the website and booklets in systematic ways to achieve desired outcomes. The EYE-2 intervention is delivered over at least 12 months in the context of standardised EIP support, by routine care co-ordinators, in routine sessions targeting routine outcomes, but is distinct from standardised care in providing a model, training, targeted approaches and co-produced engagement-focused tools to patients, family and friends to enhance engagement and outcomes.

Standardised Early Intervention in Psychosis

The comparison arm received standardised EIP alone, as outlined in the protocol and involving NICE guidelines-compliant interventions.[47] All EIP teams involved in the study were standardised, in that they were standalone services, adherent to the EIP model core principles of (1) early detection, (2) assertive engagement, (3) person and recovery focus, (4) family focus, (5) working with diagnostic uncertainty, (6) positive risk-taking and (7) providing NICE-recommended interventions.[106,107]

Training programme

Both arms received a half-day training in meaningful routine data collection. The EYE-2 training was delivered over the remaining 1.5 days. The EYE-2 training was delivered by the chief investigator, supported by the site PPI lead, 1–2 local service users/carers, and the EIP RA. Core sessions included (1) introduction to the EYE-2 intervention and resources, (2) the value of hopeful care co-ordination, (3) goal-focused care planning, (4) service user-led introduction to honest open communication, (5) carer's rights and protocol for engaging family and friends, (6) peer workers and social groups, (7) motivational interviewing (MI) for goal-focused engagement, (8) applying open communication approaches in the context of risk, mental health exacerbations, treatment and admissions, (9) the implementation process and local implementation plans and (10) the research process – ethics, consent, promotion and awareness raising. Three rounds of training were offered at each site. Additional booster training was delivered approximately 6-monthly throughout the intervention. A threshold was set for 80% of care co-ordinators and 70% of all staff to be trained in each team before the trial could start in each site.

Measures

Time to disengagement

Defined in days, from date of allocation to care co-ordinator to date of last contact following either refusal to engage with an EIP team or lack of response to EIP contact for 3 consecutive months. This definition is widely used in engagement research.[36,41,61] For participants who remained engaged until the end of the study follow-up period,

time to disengagement was treated as censored (unknown) beyond this point. People who engaged intermittently every few weeks or via text or phone were still classified as engaged. Contact with a family member only did not constitute engagement. Service users who were transferred to a service outside of the study, or to the opposite arm of the study, moved out of the UK and could not be referred to a mental health service, or were discharged by mutual agreement with the team, were no longer receiving the intervention and were deemed lost to follow-up. Engagement categorisation (engaged, disengaged, lost to follow-up) and date of last contact were determined following a detailed protocol (see *Project document 3*) based on deidentified case note data provided by the within-team RA. Ratings were conducted blind to study arm by a RA and double-rated by an experienced clinical psychologist. Discrepancies were reviewed by a third expert rater and final categorisations determined by consensus.

Health of the Nation Outcome Scales

The HoNOS[64] is the most widely employed routine clinical outcome measure in UK mental health services. It is a 12-item clinician-rated scale which covers a wide range of health and social outcomes including behavioural (aggression/agitation, self-harm, substance use), functional (cognitive and physical), mental health symptoms (psychosis, depression, other) and social problems (relationships, activities of daily living, living conditions and occupation). Each item is rated from 0 (no problem) to 4 (very severe), for the preceding 2 weeks. Scoring for HoNOS and subsequent measures is later in this chapter.

Process of recovery questionnaire

The QPR[65] is a 15-item measure, developed by psychosis service users to capture recovery. Items include social inclusion, assertiveness, motivation, positive relationships, purpose, empowerment, self-esteem, self-efficacy, meaningful activity, understanding, acceptance, enjoyment and positive risk-taking, each rated on a five-point scale from 0, strongly disagree to 4, strongly agree. The outcome is the total score for all 15 items.

DIALOG

The DIALOG[66] assesses patient-reported satisfaction with eight aspects of subjective QoL including health (mental and physical), function (work, leisure), social (friendships/family relationships), accommodation, and personal safety and three aspects of treatment satisfaction (TS; practical and mental health support, medication) all rated on a seven-point scale from 1, totally dissatisfied, to 7, totally satisfied. Scores on the DIALOG are reported as two mean subscale scores for subjective QoL and TS.

Rationale for the selection of secondary measures

The rationale for the use of the HoNOS, QPR and DIALOG as measures of mental health and self-reported recovery and QoL is that they are the NHS-England reported routine outcome measures for use in EIP services. It was necessary to use routine outcomes because we were evaluating disengagement as the primary outcome measure and using routine data would ensure we had the best chance of obtaining data on people who were disengaging.

Death

Death, including suicide, within 12 months of allocation to care co-ordinator.

Service use

Unplanned service use data collection, as advised by our GP commissioner, included days spent in hospital, A&E presentations and Section 136 use.

National Institute for Health and Care Excellence guideline interventions

Number of NICE guidelines interventions received within 12 months, derived from case notes, and including medication, CBT, family support, family intervention, physical health assessment, physical health intervention, vocational support, peer support, care programme approach (CPA) or other.

Team context questionnaire and triangulation tool

Additional data for sensitivity analyses including caseload per care co-ordinator were gathered through a team context questionnaire, supported by information from the EIP triangulation tool.[108]

Data collection procedures

Data used in the current evaluation were collected at baseline, 6 and 12 months. Three main data collection procedures were used to maximise data completeness. Primary outcome data (disengagement), demographic data, service use and NICE guidelines use were routinely recorded in case notes. These data were collated by 'within-team' RAs, transferred and entered into MACRO in deidentified format. Secondary clinician-rated and patient-reported outcomes (HoNOS; QPR; DIALOG[64–66]) were routinely collected by EIP clinicians but were also collated by 'within team' RAs and entered onto MACRO in deidentified format. RAs were also able to collect patient-reported outcomes in person, by telephone or by virtual consultation (VC) where these data had not been collected routinely, or following informed consent, from patients who had disengaged. A specially designed interview (see *Chapter 2 and Project document 6*) also enabled RAs to collect information to rate the HoNOS in these circumstances. Finally, where HoNOS data were missing, and a service user was not available to complete this by telephone, a protocol for screening case notes to derive HoNOS data was also developed (see *Project document 7*). The method used to collect data was recorded for HoNOS, QPR and DIALOG and sensitivity analyses used to evaluate the impact of data collection method on the results. Baseline comprised the first −4 to +6 weeks to allow for baseline assessments conducted in hospital immediately prior to EIP allocation; follow-up data were aimed to be collected at each time point −2/+4 weeks.

Blinding

Teams administering interventions and individual participants were not blind to allocation. A rigorous process was followed to ensure that RAs rating the primary outcome were blind to the allocation status of teams at their respective sites. RAs were either 'within team-unblinded' or 'blinded'. Within-team unblinded RAs screened clinical notes on a 6-monthly basis for patients in their teams and transferred sufficient deidentified information to MACRO to enable a second 'blinded' RA to rate the engagement status for each participant, blind to team and arm of study. The statisticians, health economists and process evaluation research team members were also blind to allocation during data collection and were only unblinded once the database had been locked, the SAP[104] had been independently reviewed and signed off and the analysis completed.

Randomisation

A statistician at the Brighton and Sussex Clinical Trials Unit generated a randomisation list comprising permuted blocks of size 2, stratified by site using a tool provided by Sealed Envelope™,[105,109] an independent online randomisation service. A team list was also randomly ordered using a random number list. To achieve statistician blinding and to ensure concealment, the randomisation list and team list were sent to an independent statistician who uploaded these to Sealed Envelope. The study research fellow (RW) requested the password-protected concealed allocations online once all the participating teams at a site had reached the threshold for care co-ordinator and staff training and were ready to start.

Power and sample size

Participants were a consecutive sample in each service. Time to disengagement was analysed using frailty analysis to adjust for clustering by team. Simulation confirmed that 10 clusters (teams) per arm (N = 950 participants in total across the 20 teams) would achieve 90% power to detect a difference corresponding to 12-month disengagement rates of 25% (standard 12-month disengagement rate from EIP service)[34–36] versus 15%, and also assuming the following: time to disengagement follows an exponential distribution; intracluster correlation coefficient of 0.05 (to be conservative in the absence of information on this parameter); loss to follow-up rate 10% per year; conservative significance level 3% to correct for inflation of type I error due to the small number of teams; variable cluster size modelled as a uniform random variable between 35 and 60; 12 months for identifying participants plus an additional 12 months of follow-up. The target reduction in disengagement and expected loss to follow-up were based on data from the original EYE pilot project, which found low levels of loss to follow-up and a reduction in disengagement of 10%. We did not anticipate any loss of teams during the trial. Simulations were conducted using the SimSam package in Stata 14[110] (see https://github.com/richard-hooper/simsam/tree/EYE2). In October 2019, the Trial Steering Committee asked us to re-evaluate the statistical power in light of the lower-than-expected rate of service user identification and to consider an extended timetable for the trial. We used recruitment figures to date to project the recruitment to each team if we identified participants for a total of 15.5 months, and calculated power assuming an additional follow-up period of either 8.5 or 12 months. This recalculation of power was done blind to the treatment allocations: simulations of power were conducted over all possible randomisations of teams stratified by site, with all other assumptions as in the original,

pre-trial power calculation above. We estimated the power to be 85% with 15.5 months' recruitment plus 8.5-month follow-up or 90% with 15.5 months' recruitment plus 12-month follow-up.

Statistical principles

Statistical software
Analyses were performed in Stata version 16.1 or later.[111]

Confidence intervals and *p*-values
Estimates, their 95% confidence intervals (CIs) and *p*-values were reported for comparisons between trial arms. The level of statistical significance was 5%.

Analysis population
Intention-to-treat (ITT) principles were followed to compare outcomes of the participants in each intervention arm.

Loss to follow-up
Participants were considered lost to follow-up if they:

- moved to a mental health service outside the study;
- moved to a service in a different arm of the trial;
- moved to a mental health service in a different country;
- died due to suicide or other cause;
- asked to be withdrawn from the trial;
- were discharged by mutual consent with no clinical need;
- needed to be withdrawn for any other reason, including any safety reason.

Engagement status of participants who were lost to follow-up was censored at the time of their withdrawal. Participants whose eligibility had been confirmed but their clinical team later revised their status as not FEP were considered post-identification exclusions due to ineligibility and were not included in the analysis. Participants who were rated blindly as disengaged were followed up as per trial protocol.

Timing of outcome assessments and protocol deviations
The primary outcome was assessed on a 6-monthly basis by detailed case note review and MACRO extracts, and indication of potential disengagement/lost to follow-up, by a RA blind to study group. Where it was deemed that further information was required to make a rating, this was fed back to the 'within-team' RA who provided this information. Primary outcome status (engaged, disengaged, lost to follow-up) was double rated by an independent clinician based on all available data. Any discrepancies were discussed to reach consensus. For those who had disengaged or been lost to follow-up, the timing of this event was retrospectively determined. Secondary outcomes were measured at 0, 6 and 12 months for all participants, not necessarily with each measure collected on the same date, and at 18 and 24 months for some, within a pre-specified window of (−2, 4) weeks either side of the due date, except for baseline for which the pre-specified window was (−4, 6) weeks and included the possibility that some data may have been collected while the participant was in an inpatient setting. Where more than one baseline value was available, we selected that which was closest to the date when the patient was allocated to their care co-ordinator. Data collected outside these periods were classed as out-of-window data collection deviations. The proportion of data collected out-of-window was presented per trial arm for each time point for the following measures: HoNOS, QPR and DIALOG. Due to the pressures of delivering clinical services, much of the secondary outcome data were collected outside the pre-specified windows. In order to accommodate this, such observations were swapped to the nearest interim (pseudo) time point that is 3, and 9 months, for the first 12 months of data collection.

Fidelity

Definition of fidelity to the intervention and how this is assessed including extent of exposure

Fidelity to the intervention was measured at three time points during the trial using self-report questionnaires administered to clinicians in each team as part of a process evaluation. Clinicians' self-reported use of the key intervention resources (1) EYE-2 booklets, (2) website with service users and (3) referrals of service users to social groups) were used to assess fidelity. For each of these components, clinicians rated the proportion of their EYE-2 service users with whom they had used the intervention resources in the previous 6 months, rated on a five-point Likert where 0 = not used; 1 = used with 0–25% of my service users; 2 = 26–50%; 3 = 51–75% and 4 = used with 76–100% of my service users.

Description of how fidelity to the intervention is presented

A composite mean fidelity score was calculated for each clinician, by averaging their individual scores indicating use of the key intervention resources with service users listed above and providing a mean composite score ranging from 0 to 4. Summary statistics for fidelity to the intervention are reported for the intervention group and individually for each cluster (team), by averaging the scores for all clinicians in each team who completed the questionnaire at each of the three time points.

Statistical analyses

Participant progress through the study was summarised using a flow diagram according to the CONSORT extension for cluster randomised trials,[112] as presented in our trial protocol and SAP.[47,104] Eligibility screening data were collected by the RA for each team. We reported the number of patients screened, the number deemed ineligible (patients who did not meet team inclusion criteria of a new FEP presentation aged 14–35, at screening) with reasons, and the number of eligible participants as a proportion of those screened. Participant loss to follow-up was summarised overall and by intervention arm. The following baseline characteristics were summarised overall and by intervention arm:

- age
- gender
- ethnicity
- duration of untreated psychosis
- level of educational attainment
- deprivation score: Index of Multiple Deprivation[113]
- substance use score on HoNOS at baseline
- symptom score on HoNOS at baseline

Statistics appropriate to the distribution of each variable were used, such as frequency and percentage for categorical variables, mean and SD for normally distributed continuous variables or median and interquartile range for skewed continuous variables.

Outcome analyses

Primary outcome modelling: time to disengagement

The original plan for the analysis was to use Cox regression with gamma-distributed shared frailty to allow for the clustering by team and use a permutation test to obtain a true significance level,[114] since there would have been a risk of inflation of the type I error from the mixed Cox regression model, owing to the relatively small number of clusters. However, in the final analysis the clustering effect was negligible (see *Results*, below), so a multivariable Cox regression model without clustering (and without the need for a permutation test) was used instead.

The proportional hazards assumption was assessed using Schoenfeld residuals. Time to disengagement or the time beyond which observations are censored (due to loss to follow-up or end of data collection) was known for all participants. Fixed effects included treatment allocation, site, age at allocation to care co-ordinator and substance misuse score (HoNOS question 3) at baseline due to the impact of substance use on engagement. We report the estimated hazard ratio, its 95% CI and the two-sided *p*-value of the test of the treatment effect.

Secondary outcomes

The following outcomes were summarised by intervention arm and time point (up to 12 months). Since, by design, not all participants were followed up at 18 and 24 months, the greatest effort was focused on collecting data at 12 months; therefore, these are the data that were used for the modelling. Outcomes to be modelled are indicated with (m).

Health of the Nation Outcome Scales

Individual item scores

We modelled the hallucinations/delusions (m) item separately (question 6).[64]

Subscale scores

- Behavioural problems (questions 1–3, range 0–12) (m)
- Impairment (questions 4 and 5, range 0–8) (m)
- Symptoms (questions 6–8, range 0–12) (m)
- Social (questions 9–12, range 0–16) (m)
- Overall score (sum of 12 questions, range 0–48) (m)

Process of recovery questionnaire

Overall score (sum of 15 questions, range 0–60) (m).[65]

DIALOG[66]

- subjective QoL (mean of questions 1–8, range 1–7) (m)
- treatment satisfaction (mean of questions 9–11, range 1–7) (m)

Death

Death, including suicide, within 12 months of allocation to care co-ordinator.

Service use

Unplanned service use data collection, as advised by our GP commissioner, included:

- number of days spent in hospital (m)
- number of A&E presentations (m)
- number of instances of Section 136 use

The primary end point was at 12 months (m).

National Institute for Health and Care Excellence guideline interventions

Number of NICE guidelines interventions within 12 months.

Secondary outcome modelling

Health of the Nation Outcome Scales, QPR and DIALOG were analysed using mixed-effects regression analysis of all non-missing data [valid if outcomes are missing at random (MAR)] appropriate to distribution, with a random effect for time point. The planned random effect for team was not required as clustering was negligible. From each model, we report the estimated treatment effect, its 95% CI and *p*-value. Additionally, for HoNOS, QPR and DIALOG models, robust standard errors were estimated as the assumption of normality of the residuals was not appropriate.

For the service use outcomes, multivariable Poisson regression with robust standard errors was fitted to nights in hospital and multivariable logistic regression was fitted to accident and emergency (A&E) visits instead due to the lower number of visits. No model was fitted to Section 136 use as there were few occurrences.

We report the estimated incidence rate ratio for the treatment effect and its 95% CI. Models include the following fixed effects:

- site
- treatment allocation
- baseline score (HoNOS only)
- age at allocation to care co-ordinator

Time point

Observations for HoNOS, QPR and DIALOG that fell outside the collection windows for each time point were quantified and visualised. Intermediate (pseudo) time points at m3 and m9 were created between the main time points (m0, m6 and m12), and observations assigned to the closest empty time point. For HoNOS, baseline observations were not reassigned to later time points as data collection occurred close to baseline, and baseline score was included as a covariate in the model. For QPR and DIALOG, baseline data collection could occur after true baseline, so these observations may have been reassigned to their closest empty time point. The baseline score was included in the outcome variable and an interaction between treatment allocation and time was included in these models, without the treatment allocation (intervention) main effect, as this would represent a comparison of the outcome at baseline. Omission of the treatment allocation main effect is equivalent to assuming equality of outcome between groups at baseline.[115]

Missing data for secondary outcomes

The specified analysis of HoNOS, QPR and DIALOG assumed that unobserved participants are MAR. For each of these outcomes, we examined the sensitivity of conclusions to this by imputing outcome data, at month 12 only, departing from this assumption.[116–119] This was performed using $\Delta = \Delta\text{outcome} + Y_1P_1 - Y_0P_0$, where Δ is the treatment effect under MNAR, Δoutcome is the treatment effect, estimated with the 'margins' command in Stata, from each secondary analysis model, Y_1 and Y_0 are the assumed mean participant responses of those missing data in the 'EYE-2 intervention plus sEIP service' and 'sEIP service alone' arms, respectively, and P_1 and P_0 are the proportions of participants excluded from analysis in their respective arms. Y_0 were varied for each outcome variable, and for each value of Y_0, Y_1 was set equal to: $\{Y_0 - x, Y_0, Y_0 + x\}$. The assumed mean response (Y_0) of participants missing data in the 'sEIP service alone' arm was varied across the following values: HoNOS: (5, 10, 15, 20, 25, 30, 35, 40, 45); QPR: (10, 20, 30, 40, 50); and DIALOG: each subscale (2, 3, 4, 5, 6). The assumed mean response (Y_1) of participants missing data in the 'EYE-2 intervention plus sEIP service' arm was set equal to $Y_0 + x$ for each x as follows: HoNOS: (−5, 0, 5); QPR: (−10, 0, 10); DIALOG: (−1, 0, 1). We calculated CIs for the treatment effect using the standard error of Δoutcome, assumed approximately equal to the standard error of Δ, from the complete case analysis. An example of the application of this approach can be found in Gillard *et al.*[120]

Additional analyses

Sensitivity analyses

Sensitivity analyses were conducted for the following:

HoNOS, QPR and DIALOG models including only observations collected in window.

Method of data collection for HoNOS: We explored the impact of different methods of collection of HoNOS, namely whether there were differences between outcomes collected by care co-ordinators and those collected by RAs via case notes screen (with/without checking by care co-ordinator) or telephone interview with the participant, by fitting a model which included only participants whose data were collected by their care co-ordinator.

Impact of the COVID-19 pandemic: We used the date of the first UK lockdown (23 March 2021) and fitted two models for each of disengagement, HoNOS, QPR and DIALOG outcomes up to 12 months (1) including only participants with baseline measure ascertained before lockdown and (2) including only participants with baseline data collected after lockdown started and pooled the estimates from each pair of models using a fixed-effects meta-analysis.

Subgroup analyses

In order to test for the impact of factors that were hypothesised to influence engagement or implementation of the intervention according to the logic model, the primary analysis model was repeated in the following subgroup analyses (in separate models) by fitting an interaction term between the subgroup variable at baseline and the treatment allocation variable as follows:

- substance misuse – binary 2, 3 or 4 versus 0 or 1 on HoNOS item 3
- symptom severity (HoNOS symptom score)
- ethnic group (mixed/other, any black, any Asian vs. any white)
- educational attainment (degree, vocational, A-level, GCSE vs. none)
- deprivation category (high vs. low)
- sex (male vs. female only)

Additionally for disengagement and HoNOS, QPR and DIALOG, using the team context questionnaire/EIP triangulation tool:[108]

- average caseload per care co-ordinator in the team dichotomised based on previously recommended EIP caseload size (high > 15 vs. low < 15)
- funding level per team (high vs. low)

Harms

As high number of serious adverse events (SAEs) were anticipated in this large EIP population, we planned to record only SAEs that resulted in death, were life-threatening, required new or prolonged hospitalisation, resulted in persistent or significant disability/incapacity, or any other medically significant event, and were possibly, probably, or definitely related to the study intervention, by intervention arm and overall. See our trial protocol for a detailed description.

Results

This section covers the results for the EYE-2 effectiveness study as set out in the SAP.

Training outcomes

A total of 462 staff working in the 20 participating EIP teams were invited to attend training; 190 were invited to attend the data collection training only (services randomised to the sEIP arm) and 272 to attend both the data collection and intervention training (from services randomised to the EYE-2 + sEIP intervention arm). Of the total number of staff working within teams, 427 (92%) consented to take part in training [175 (92%) from teams randomised to sEIP and 252 (92%) from teams randomised to the EYE-2 intervention] and 336 (73%) attended training [132 (70%) from teams randomised to sEIP and 204 (75%) from teams randomised to the EYE-2 intervention].

Of the 224 care co-ordinators or team leads across the 20 teams (87 from teams randomised to sEIP and 137 from teams randomised to the EYE-2 intervention), 187 (84%) attended training; 71 (82%) from teams randomised to sEIP and 116 (85%) from teams randomised to the EYE-2 intervention. Attendance rates met the minimum threshold of staff attendance set for teams of at least 70% of the entire team and 80% of care co-ordinators/team leads required to attend training.

Demographic and mean data reported are based on the available data from all staff who completed pre-training or post-training surveys.

Table 2 presents the baseline demographics for staff who attended the training programmes and completed demographic survey questions. The mean age was 38, the majority were white, female and either nurses, social workers, occupational therapists, or psychologists.

Full details of the training are available in *Appendix 5*. Both training programmes were well-accepted, with staff rating training material moderately highly in terms of helpfulness [5.83 (SD = 0.65, range = 3.33–7) out of 7 for the intervention materials and 5.84 (SD = 0.86, range = 2.57 – 7) out of 7 for the data collection training]. The training programmes led to increases in confidence in using EYE-2 engagement approaches, $b = 0.72$, $t(162.93) = 13.67$,

TABLE 2 Baseline demographic characteristics of all staff who attended the training programmes and completed demographic survey questions

	Intervention training (*N* = 197)[a]		Data collection training (*N* = 282)[b]	
	***M* (SD)**	**Range**	***M* (SD)**	**Range**
Age	38.24 (10.14)	20–77	38.96 (10.41)	18–67
Sex	*n*	%	*n*	%
Female	143	74.1	215	76.5
Male	50	25.9	65	23.1
Ethnicity				
White	162	84.8	224	80.6
Black British	8	4.2	11	4.0
Black African/Afro-Caribbean	9	4.7	21	7.6
Asian	7	3.7	10	3.6
Mixed	5	2.6	8	2.9
Other	–	–	4	1.4
Core discipline/role				
Nurse	81	43.0	115	43.6
Social worker	31	16.5	45	17.0
Occupational therapist	19	10.1	26	9.8
Support worker	14	7.4	25	9.5
Psychologist	24	12.8	34	12.9
Psychiatrist	10	5.3	11	4.2
Administrator	1	0.5	4	1.5
MSc student	1	0.5	1	0.4
Pharmacist	1	0.5	2	0.8
Vocational worker	2	0.5	–	–
RA	1	0.5	–	–
Assistant psychologist	3	1.6	1	0.4

a Data were missing completely for seven people from the intervention training.
b Fifty-four people from the data collection training. In the intervention training, data on sex were missing for a further four people, ethnicity for six people and role for nine people. In the data collection training, data on sex were missing for 2 people, ethnicity for 4 people and role for 18 people.

$p < 0.001$, and in collecting outcome data, $b = 1.33$, $t(268.47) = 15.94$, $p < 0.001$ pre to post training. Attitudes were highly positive towards implementation of the EYE-2 intervention [mean rating of 5.88 (SD = 0.74, range = 3.43–7) out of 7]. The data collection training also led to increases in beliefs about the importance of collecting outcome data pre to post training, $b = 0.78$, $t(268.74) = 11.85$, $p < 0.001$, and staff reported a high likelihood of collecting outcome data following training [6.08 (SD = 1.23, range = 1–7) out of 7].

Patient identification and randomisation

Figure 5 shows the CONSORT diagram.

Baseline participant characteristics

Demographics

Participant characteristics were reasonably well balanced between trial arms (*Table 3*). Levels of deprivation were slightly greater in EYE-2 + sEIP versus sEIP only, as was the proportion of non-white ethnicity. Educational attainment was, on average, slightly lower in the EYE-2 + sEIP arm compared to the sEIP-only arm.

Primary outcome analysis

Primary outcome summaries

Overall, 15.9% of participants disengaged during the trial, with very similar proportions in each arm (*Table 4*). Refusal to engage with EIP team was the most common reason for disengagement. Time to disengagement was slightly shorter in the EYE-2 + sEIP arm than in the sEIP alone arm. *Figure 6* shows the Kaplan–Meier curves for each group in very close proximity to one another.

Primary outcome model

Disengagement ratings were 85% concordant between the first- and second-blind raters. Remaining cases were agreed in consensus with the third expert rater.

The Multivariable Cox regression was fitted to 1005 participants (160 disengagements), adjusting for site, age and substance use at baseline (HoNOS question 3: problem-drinking or drug-taking grouped as no/minor problems vs. mild/moderate/severe). Twenty-two participants (three disengagements) were excluded from the model due to missing responses to HoNOS substance use at baseline.

The adjusted hazard ratio (HR) (95% CI) for EYE-2 + sEIP to sEIP only was 1.07. This indicates the observed hazard of disengagement was slightly higher in the EYE-2 + sEIP arm though, within limits of 95% confidence, we estimated the hazard ratio to be between 0.76 and 1.49, hence ruling out a reduction of more than 24% in the risk of disengagement in the intervention arm ($p = 0.713$).

A post hoc sensitivity analysis to assess the effect of further adjustment for the baseline variables IMD (binary, Low 6–10 vs. High 1–5), ethnicity (binary, Any white background vs. Any mixed, black, Asian or other background) and gender was performed, as given the cluster randomisation, imbalance of these variables was possible. The adjusted HR (95% CI) for EYE-2 + sEIP to sEIP only was 1.03 (0.73–1.46). This model included 934 participants (149 disengagements). The HR (95% CI) after additional adjustment for education level (binary, No educational awards vs. GCSE or above) was 1.27 (0.84 to 1.92), but the participants included in the model was reduced to 703 (118 disengagements), due to missing data. These were consistent with the results of the primary analysis.

Secondary outcome analyses

Secondary outcome collection windows and missing values

Table 5 shows that the majority of HoNOS data were collected in window at baseline, though this reduced by 6 months and further again at 12 months. A minority of QPR and DIALOG data were collected in window at baseline, though this increased over time. At 12 months, data was either collected or unavailable due to loss to follow-up for 79.2% of HoNOS data, but only 50.6% QPR and 49.4% of DIALOG.

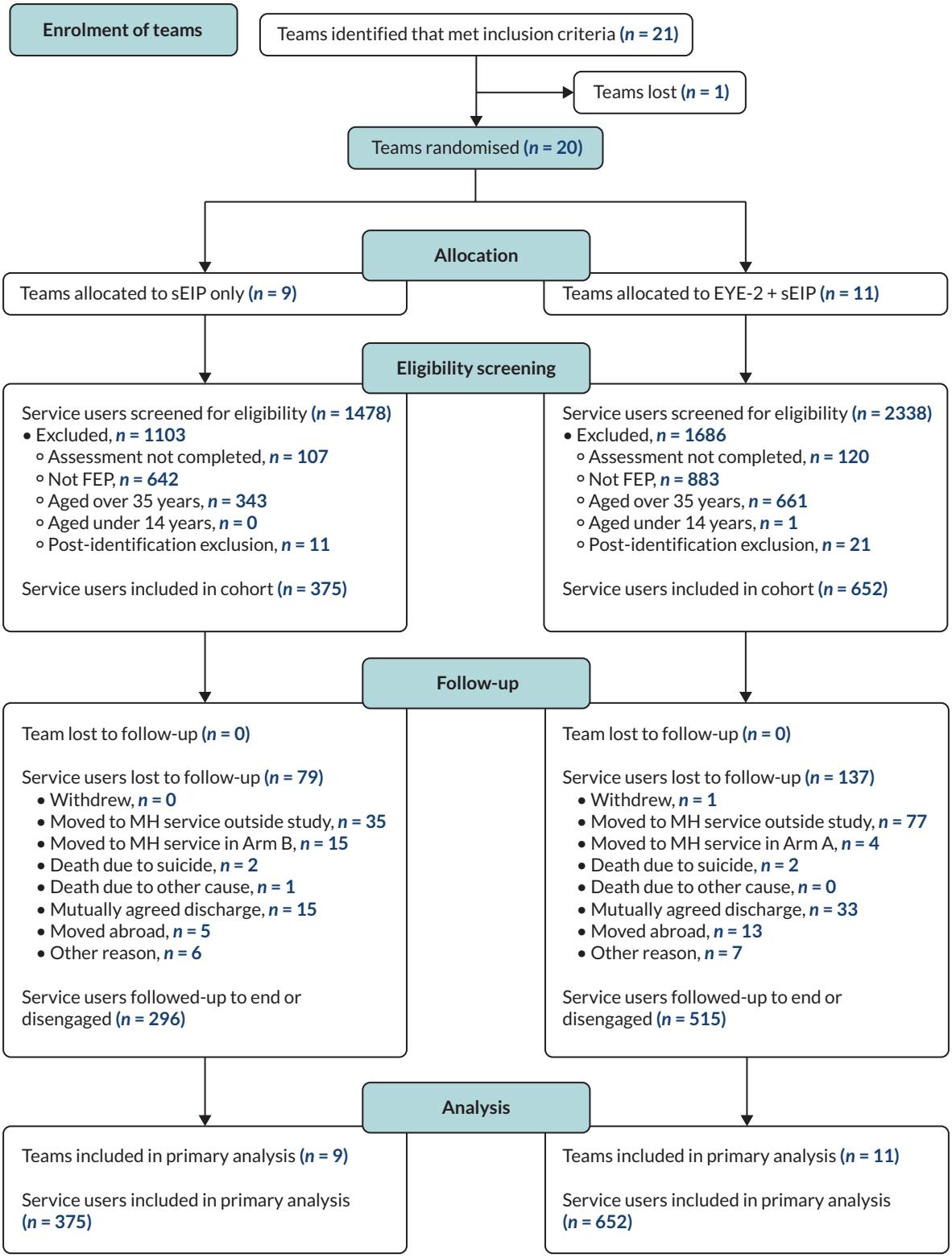

FIGURE 5 Study CONSORT diagram.[105]

Unplanned service use outcome summaries

Table 6 shows that 42% of the sample had at least one hospital admission, 20% had at least one A&E visit, and 4% had a Section 136 use. Proportions were generally similar across arms, although the median nights spent in hospital for people who were admitted was higher in the sEIP arm compared to the EYE-2 arm.

TABLE 3 Baseline participant characteristics by intervention arm

	sEIP only			EYE-2 + sEIP			Overall		
	Mean	**SD**	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	***n***
Age	24.9	5.5	375	25.2	5.4	652	25.1	5.4	1027
HoNOS symptoms score at baseline (range 0–12)	5.6	2.4	360	5.3	2.4	615	5.4	2.4	975
	Median	**IQR**	***n***	**Median**	**IQR**	***n***	**Median**	**IQR**	***n***
Duration of untreated psychosis (days)	77.0	32.0–242.0	297	76.0	27.0–294.0	517	77.0	29.0–264.0	814
Indices of multiple deprivation decile	4.0	2.0–7.0	372	3.0	2.0–5.0	644	4.0	2.0–6.0	1016
	n	**%**		***n***	**%**		***n***	**%**	
Substance use (HoNOS Question 3)									
No problem	202	54.9		367	57.6		569	56.6	
Minor problem requiring no action	41	11.1		68	10.7		109	10.8	
Mild problem but definitely present	59	16.0		124	19.5		183	18.2	
Moderately severe problem	55	14.9		65	10.2		120	11.9	
Severe to very severe problem	11	3.0		13	2.0		24	2.4	
Total	368	100.0		637	100.0		1005	100.0	
Indices of multiple deprivation decile (binary)									
Low (6–10)	136	36.6		167	25.9		303	29.8	
High (1–5)	236	63.4		477	74.1		713	70.2	
Total	372	100.0		644	100.0		1016	100.0	
Ethnicity									
White British	165	44.4		228	35.5		393	38.7	
White Irish	1	0.3		4	0.6		5	0.5	
Any other white background	38	10.2		65	10.1		103	10.1	
White and Black Caribbean	2	0.5		9	1.4		11	1.1	
White and Black African	6	1.6		19	3.0		25	2.5	
Any other mixed background	17	4.6		23	3.6		40	3.9	
Indian	7	1.9		11	1.7		18	1.8	
Pakistani	15	4.0		14	2.2		29	2.9	
Bangladeshi	2	0.5		2	0.3		4	0.4	
Any other Asian background	21	5.6		32	5.0		53	5.2	
Caribbean	8	2.2		25	3.9		33	3.3	
African	32	8.6		79	12.3		111	10.9	
Any other black background	21	5.6		81	12.6		102	10.0	
Chinese	2	0.5		2	0.3		4	0.4	

continued

TABLE 3 Baseline participant characteristics by intervention arm (*continued*)

	sEIP only		EYE-2 + sEIP		Overall	
	n	%	*n*	%	*n*	%
Any other ethnic group	15	4.0	21	3.3	36	3.5
Not stated	20	5.4	28	4.4	48	4.7
Total	372	100.0	643	100.0	1015	100.0
Ethnicity (binary)						
Any white background	204	58.0	297	48.3	501	51.8
Any mixed, black, Asian or other background	148	42.0	318	51.7	466	48.2
Total	352	100.0	615	100.0	967	100.0
Gender						
Male	253	67.5	400	61.3	653	63.6
Female	122	32.5	247	37.9	369	35.9
Non-binary/not specified	0	0.0	5	0.8	5	0.5
Total	375	100.0	652	100.0	1027	100.0
Education level						
No educational awards received	36	13.1	79	16.3	115	15.2
GCSE grade A–G NVQ level 1 or 2 etc.	79	28.8	132	27.2	211	27.8
A-Level, NVQ level 3, BTEC etc.	100	36.5	148	30.5	248	32.7
Undergraduate, NVQ level 4 or 5, BTEC HND, Foundation degree etc.	54	19.7	107	22.1	161	21.2
Postgraduate (Masters), MCGI, Diploma, Doctoral, FCGI etc.	5	1.8	19	3.9	24	3.2
Total	274	100.0	485	100.0	759	100.0

Service use models

Number of nights in hospital

The robust Poisson regression model for number of nights in hospital was fitted to 866 participants, adjusting for site, age and substance use (HoNOS Question 3 at baseline problem-drinking or drug-taking grouped as no/minor problems vs. mild/moderate/severe). One hundred and sixty-one participants were excluded due to missing the outcome (n = 144) or substance use at baseline (n = 22) (five were missing both).

The adjusted incidence rate ratio (IRR) (95% CI) for EYE-2 + sEIP to sEIP only was 0.83 (0.61–1.13, p = 0.234). This IRR indicates the incidence rate for number of nights in hospital was slightly lower in the EYE-2 + sEIP arm, but there was no evidence of a difference between arms.

Accident and emergency visits

The logistic regression model for A&E visits (174 had ≥ 1 visit vs. 709 who did not visit A&E) was fitted to 866 participants, adjusting for site, age and substance use [HoNOS Question 3 at baseline (problem-drinking or drug-taking

TABLE 4 Summaries of disengagement and time to disengagement (in days) by intervention arm

	sEIP only			EYE-2 + sEIP			Overall		
	n	%		*n*	%		*n*	%	
Disengaged									
No	316	84.3		548	84.0		864	84.1	
Yes	59	15.7		104	16.0		163	15.9	
Total	375	100.0		652	100.0		1027	100.0	
Reason for disengagement									
Refusal to engage with EIP team	20	33.9		32	30.8		52	31.9	
Lack of response to EIP contact for 3 consecutive months	17	28.8		30	28.8		47	28.8	
Left area or country with no ongoing transfer of care and discharged as a result	8	13.6		20	19.2		28	17.2	
Other reason	14	23.7		22	21.2		36	22.1	
Total	59	100.0		104	100.0		163	100.0	
	Median	**IQR**	***n***	**Median**	**IQR**	***n***	**Median**	**IQR**	***n***
Time to disengagement	278.0	136.0–433.0	59	253.0	86.5–378.5	104	258.0	109.0–395.0	163

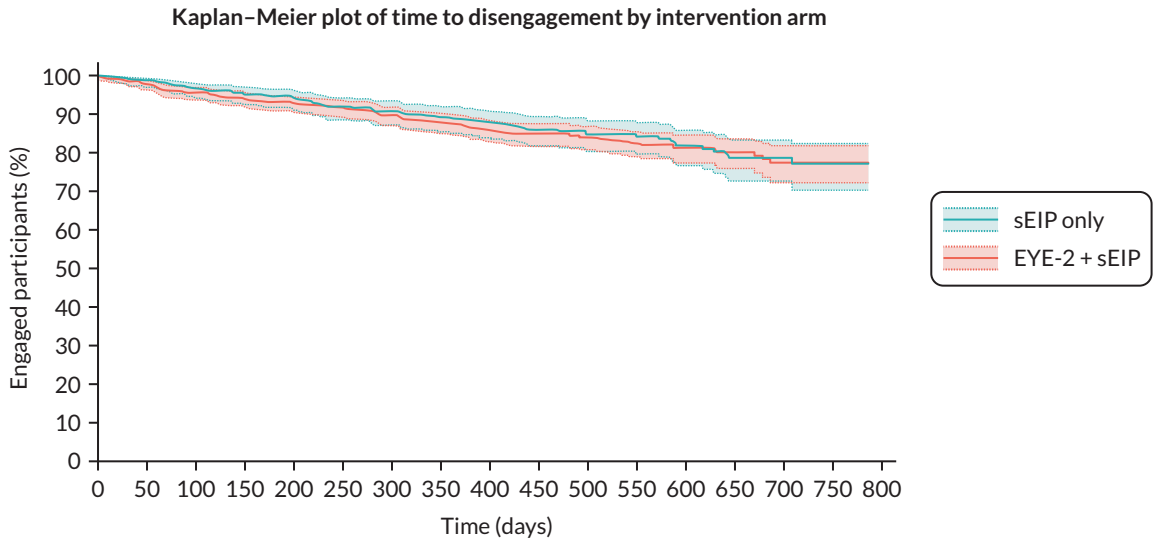

FIGURE 6 Kaplan–Meier plot of time to disengagement (in days) by arm with 95% confidence intervals.

grouped as no/minor problems vs. mild/moderate/severe)]. One hundred and sixty-one participants were excluded due to missing the outcome (144) or HoNOS Q3 at baseline (22) (5 were missing both).

The adjusted odds ratio (OR) (95% CI) for EYE-2 + sEIP to sEIP only was 0.81 (0.57 to 1.17, $p = 0.262$). This OR indicates the odds for at least one A&E visit was slightly lower in the EYE-2 + sEIP arm, but there was insufficient evidence to conclude there was a difference between arms.

TABLE 5 Data collected within or outside of collection windows for HoNOS, QPR, DIALOG and service use outcomes, and reasons for missingness (loss to follow-up, disengagement or not collected)

	Collected data						Missing data							
	Collected in window		Collected out of window		Data collected		Unavailable due to loss to follow-up		Missing due to disengagement		Missing due to not collected		Overall missing	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
HoNOS														
m0	864	85.5	147	14.5	1011	98.4	0	0.0	0	0.0	16	1.6	16	1.6
m6	520	60.9	334	39.1	854	83.2	77	7.5	45	4.4	51	5.0	173	16.8
m12	393	58.6	278	41.4	671	65.3	143	13.9	95	9.3	118	11.5	356	34.7
QPR														
m0	282	45.3	340	54.7	622	60.6	0	0.0	0	0.0	405	39.4	405	39.4
m6	209	45.9	246	54.1	455	44.3	83	8.1	57	5.6	432	42.1	572	55.7
m12	208	55.6	166	44.4	374	36.4	146	14.2	110	10.7	397	38.7	653	63.6
DIALOG														
m0	277	46.3	321	53.7	598	58.2	0	0.0	0	0.0	429	41.8	429	41.8
m6	201	46.5	231	53.5	432	42.1	82	8.0	57	5.6	456	44.4	595	57.9
m12	202	56.0	159	44.0	361	35.2	146	14.2	110	10.7	410	39.9	666	64.8
Service use outcomes														
m6	N/A		N/A		1014	98.7	0	0.0	0	0.0	13	1.3	13	1.3
m12	N/A		N/A		883	86.0	85	8.3	26	2.5	33	3.2	144	14.0

TABLE 6 Summary of number of nights in hospital, number of A&E visits and number of Section 136 uses, up to month 12, by intervention arm

	sEIP only			EYE-2 + sEIP			Overall		
	Median	IQR	*n*	Median	IQR	*n*	Median	IQR	*n*
Number of nights in hospital up to m12	0	0–26	331	0	0–21	552	0	0–22	883
Number of nights in hospital up to m12 for participants with at least one night in hospital	33	16–67	139	26	10–49	231	27	12–55	370
	n	%		*n*	%		*n*	%	
Number of A&E visits up to m12									
0	264	79.8		445	80.6		709	80.3	
1	48	14.5		67	12.1		115	13.0	
2	12	3.6		20	3.6		32	3.6	
3	5	1.5		12	2.2		17	1.9	
4	0	0.0		3	0.5		3	0.3	
5	1	0.3		2	0.4		3	0.3	
6	1	0.3		1	0.2		2	0.2	
9	0	0.0		1	0.2		1	0.1	
28	0	0.0		1	0.2		1	0.1	
Total	331	100.0		552	100.0		883	100.0	
A&E visit(s) made up to m12									
No	264	79.8		445.0	80.6		709.0	80.3	
Yes	67	20.2		107.0	19.4		174.0	19.7	
Total	331	100.0		552	100.0		883	100.0	
Number of Section 136 uses up to m12									
0	321	97.0		528	95.7		849	96.1	
1	8	2.4		22	4.0		30	3.4	
2	2	0.6		2	0.4		4	0.5	
Total	331	100.0		552	100.0		883	100.0	

Health of the Nation Outcome Scales, questionnaire on the process of recovery and DIALOG analyses

Treatment of missing data for the questionnaire on the process of recovery and DIALOG

Missing values for QPR and DIALOG QoL questions were replaced with the average overall response if there was missing data but 80% or more of the questions had been completed. Missing values were not replaced for the TS subscale as this consists of only three questions, so could not be 80% or more complete with missing data (see *Appendix 4*, *Table 32*).

Data collection windows for Health of the Nation Outcome Scales, questionnaire on the process of recovery and DIALOG

HoNOS, QPR and DIALOG data collected within and outside of data collection windows at baseline, 6 and 12 months, by intervention arm are presented for information in *Appendix 4*, *Table 33*.

Visual summaries of dates of data collection compared to collection windows

Figure 7 shows an example of how collection dates for QPR related to expected collection windows at each time point. Only the London site is shown as patterns were similar across sites. DIALOG is not shown as its pattern of collection was very similar to that of QPR, and HoNOS is shown for comparison in *Appendix 4*, *Figure 26*.

Reassigning data to closest empty time points

Due to the extent of data collected out of window, intermediate time points (m3 and m9) were created, and data were reassigned to the closest empty time point (except for HoNOS at baseline, which was not reassigned). *Appendix 4*, *Figures 27* and *28* show the effect of reassignment to closest time points for QPR and HoNOS in London as examples.

Health of the Nation Outcome Scales, questionnaire on the process of recovery and DIALOG numbers of participants after time point reassignment

The number of data collections at each time point after reassignment are shown in *Appendix 4* (see *Table 34*). Due to the low numbers assigned to the intermediate time point at month 3 for HoNOS, this time point was not included in the HoNOS modelling analyses.

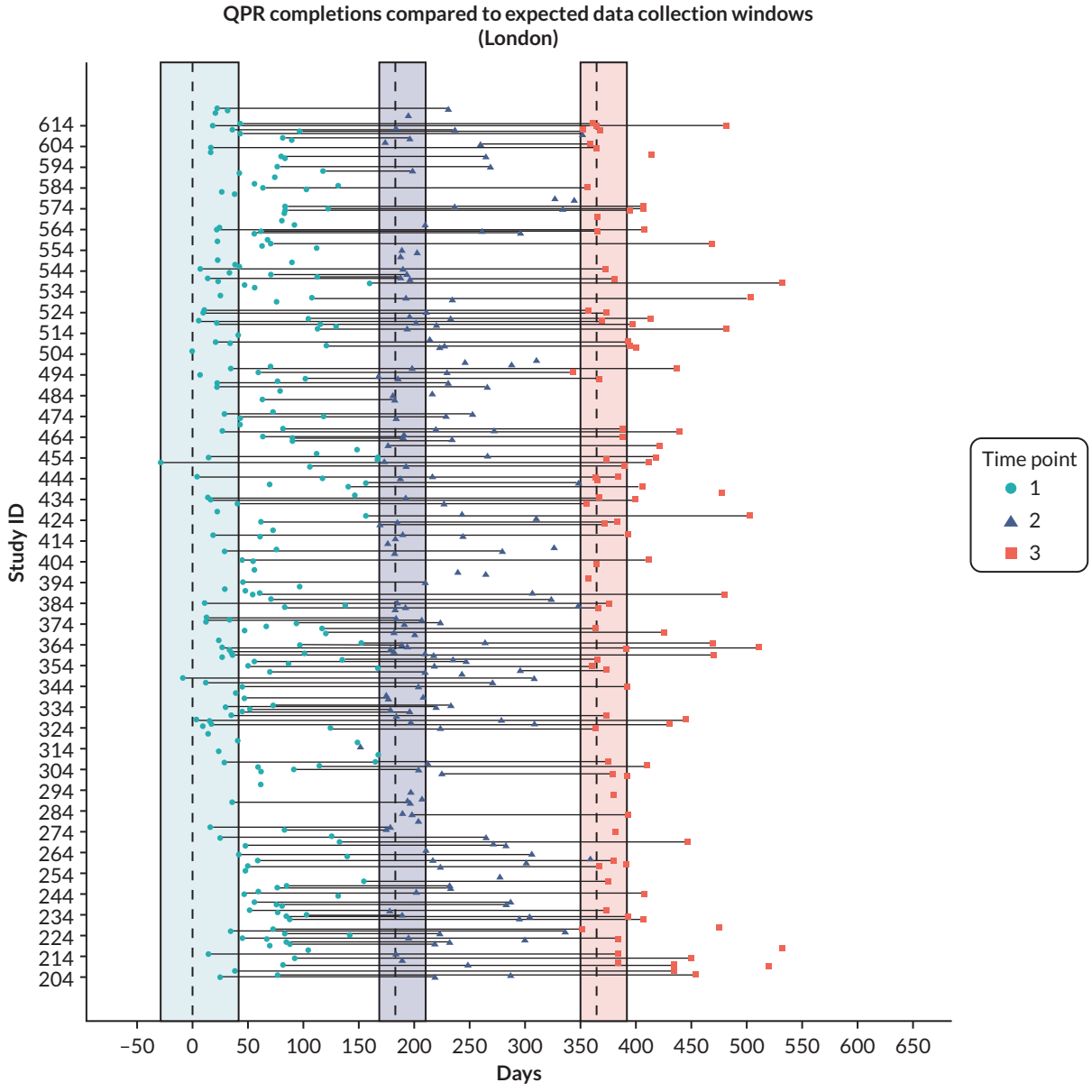

FIGURE 7 Questionnaire on the process of recovery completions compared to time point windows in London.

Health of the Nation Outcome Scales descriptive summaries

Health of the Nation Outcome Scales total, subscale and symptom scores across arm and time arm are presented in *Table 7*. Scores are generally low and drop most between baseline and 6 months. Symptom scores are comparatively greater than other subscale scores. Median baseline scores are all lower in the sEIP arm compared to the EYE-2 arm.

Questionnaire on the process of recovery and DIALOG descriptive summaries

Table 8 presents recovery (QPR), QoL and TS (DIALOG) scores by arm and over time. Scores appear to increase gradually and similarly across arms.

Health of the Nation Outcome Scales modelling

Table 9 presents the adjusted coefficients for HoNOS scores over time. The adjusted coefficient for each time point represents the mean difference in score for the EYE-2 + sEIP arm compared to the sEIP only arm. There was no evidence for a difference between arms for any scale at any time point.

Questionnaire on the process of recovery score and DIALOG quality of life and treatment satisfaction scores modelling

The linear mixed-effects regression model for recovery (QPR) score was fitted to 775 participants, the model for DIALOG QoL and TS models were fitted for 753 and 757 participants, respectively, adjusting for site, age and time point, with an interaction between arm and time point. Only participants with complete data including data for at least one time point and all covariates were included. The difference between arms at baseline was constrained to 0.

The adjusted coefficients (*Table 10*) did not consistently favour either arm and there was no evidence of differences in QPR score, or DIALOG QoL or TS scores, between arms over time.

Health of the Nation Outcome Scales, questionnaire on the process of recovery and DIALOG scores over time

Table 11 presents the adjusted HoNOS scores over time and by arm, as derived from the models.

Questionnaire on the process of recovery score and DIALOG quality of life and treatment satisfaction scores over time

Table 12 presents the adjusted QPR recovery scores, DIALOG QoL and TS scores over time and by arm, as derived from the models.

Health of the Nation Outcome Scales, questionnaire on the process of recovery and DIALOG scores over time summary

Finally, in relation to the HoNOS, QPR and DIALOG outcomes, *Figure 8* presents the visualisation of these scores over time and by arm. All outcomes improved similarly in both arms. HoNOS scores improved between baseline (m0) and 6 months for hallucinations/delusions, overall and for all subscales except impairment. QPR score improved at each time point from baseline. DIALOG QoL score improved at each time point from baseline. DIALOG TS score improved at m3 and m6 from baseline and remained relatively steady after m6.

Missing data for HoNOS overall score, questionnaire on the process of recovery score and DIALOG quality of life and treatment satisfaction scores

Linear models were fitted with month 12 data as the outcome, adjusting for site, age and baseline score (for HoNOS only), to provide insight into the effects of data that was not MAR. Results from this analysis are shown in *Appendix 4*, *Tables 35–38*.

Overall, the results indicate that the MAR analysis is not robust to departures from that assumption for HoNOS, QPR or DIALOG, as situations where the missing value is assumed to be different between arms leads to one or other of the arms being favoured. In some situations, for QPR and DIALOG, the sEIP arm tends to be more favoured when the missing values are assumed to be equal.

TABLE 7 Health of the Nation Outcome Scales hallucinations and delusions, subscale scores and overall score at baseline (m0), 6 months (m6), 9 months (m9) and 12 months (m12), by intervention arm

	sEIP only			EYE-2 + sEIP			Overall		
	Median	IQR	*n*	Median	IQR	*n*	Median	IQR	*n*
Problems associated with hallucinations and delusions (range 0–4)									
m0	3.0	2.0–3.0	370	2.0	2.0–3.0	639	3.0	2.0–3.0	1009
m6	1.0	0.0–2.0	229	1.0	0.0–2.0	382	1.0	0.0–2.0	611
m9	1.0	0.0–2.0	79	1.0	0.0–2.0	135	1.0	0.0–2.0	214
m12	1.0	0.0–2.0	253	1.0	0.0–2.0	426	1.0	0.0–2.0	679
HoNOS behavioural problems score (range 0–12)									
m0	3.0	1.0–4.0	367	2.0	1.0–4.0	629	2.0	1.0–4.0	996
m6	1.0	0.0–2.0	215	1.0	0.0–2.0	362	1.0	0.0–2.0	577
m9	1.0	0.0–2.0	78	1.0	0.0–2.5	128	1.0	0.0–2.0	206
m12	1.0	0.0–2.0	251	1.0	0.0–2.0	420	1.0	0.0–2.0	671
HoNOS impairment score (range 0–8)									
m0	1.0	0.0–2.0	368	0.0	0.0–2.0	623	1.0	0.0–2.0	991
m6	1.0	0.0–2.0	216	1.0	0.0–2.0	357	1.0	0.0–2.0	573
m9	0.0	0.0–2.0	79	1.0	0.0–2.0	133	1.0	0.0–2.0	212
m12	1.0	0.0–2.0	246	1.0	0.0–2.0	419	1.0	0.0–2.0	665
HoNOS symptoms score (range 0–12)									
m0	6.0	4.0–7.5	360	5.0	4.0–7.0	615	5.0	4.0–7.0	975
m6	4.0	1.0–5.0	219	3.0	1.0–5.0	356	3.0	1.0–5.0	575
m9	3.0	2.0–5.0	77	3.0	2.0–6.0	131	3.0	2.0–5.5	208
m12	3.0	2.0–6.0	245	3.0	2.0–5.0	415	3.0	2.0–5.0	660

TABLE 7 Health of the Nation Outcome Scales hallucinations and delusions, subscale scores, and overall score at baseline (m0), 6 months (m6), 9 months (m9) and 12 months (m12), by intervention arm (*continued*)

	sEIP only			EYE-2 + sEIP			Overall		
	Median	IQR	*n*	Median	IQR	*n*	Median	IQR	*n*
HoNOS social score (range 0–16)									
m0	4.0	2.0–6.0	361	3.0	1.0–5.0	603	4.0	2.0–6.0	964
m6	3.0	1.0–6.0	219	3.0	1.0–5.0	357	3.0	1.0–5.0	576
m9	3.0	1.0–6.0	77	3.0	1.0–5.0	127	3.0	1.0–5.0	204
m12	3.0	1.0–5.0	246	3.0	1.0–5.0	412	3.0	1.0–5.0	658
HoNOS overall score (range 0–48)									
m0	14.0	10.0–18.0	349	12.0	8.0–16.0	582	13.0	9.0–17.0	931
m6	9.0	4.0–15.0	193	8.0	4.0–13.0	315	8.0	4.0–13.0	508
m9	8.0	4.0–13.5	76	8.0	4.0–14.0	125	8.0	4.0–14.0	201
m12	9.0	5.0–14.0	235	9.0	4.0–13.0	400	9.0	5.0–14.0	635

TABLE 8 Questionnaire on the process of recovery and DIALOG QoL and TS scores at baseline, m3, m6, m9 and m12, by intervention arm. The first QPR/DIALOG score collected, either at m0 or m3 is summarised as 'm0 and m3 combined'

	sEIP only			EYE-2 + sEIP			Overall		
	Median	IQR	*n*	Median	IQR	*n*	Median	IQR	*n*
QPR total score (range 0–60)									
m0	41.0	27.0–47.0	138	39.0	28.0–48.0	173	39.0	27.0–47.0	311
m3	41.0	30.5–45.0	108	41.0	33.0–47.0	170	41.0	32.0–47.0	278
m0 and m3 combined	41.0	29.0–46.0	246	41.0	31.0–47.0	343	41.0	30.0–47.0	589
m6	42.0	35.0–46.0	138	42.0	33.0–46.0	169	42.0	35.0–46.0	307
m9	44.0	35.0–48.0	62	43.0	34.0–49.0	101	43.0	34.0–48.0	163
m12	44.0	36.0–49.0	158	43.0	37.0–49.0	235	44.0	36.0–49.0	393
DIALOG subjective QoL score (range 1–7)									
m0	4.5	3.5–5.5	133	4.6	3.8–5.1	169	4.5	3.6–5.4	302
m3	4.8	4.0–5.4	97	4.9	4.1–5.6	166	4.9	4.1–5.5	263
m0 and m3 combined	4.8	3.8–5.5	230	4.8	4.0–5.4	335	4.8	3.9–5.4	565
m6	5.0	4.3–5.6	131	5.0	4.3–5.6	163	5.0	4.3–5.6	294
m9	5.1	4.3–5.6	59	5.0	4.3–5.5	93	5.0	4.3–5.5	152
m12	5.1	4.5–5.8	154	5.0	4.3–5.6	227	5.0	4.4–5.6	381
DIALOG TS score (range 1–7)									
m0	5.0	4.3–6.0	135	5.2	4.3–6.0	162	5.0	4.3–6.0	297
m3	5.3	4.7–6.0	96	5.7	4.7–6.0	164	5.3	4.7–6.0	260
m0 and m3 combined	5.3	4.7–6.0	233	5.3	4.3–6.0	328	5.3	4.3–6.0	561
m6	6.0	5.2–6.3	132	5.7	5.0–6.3	167	5.7	5.0–6.3	299
m9	6.0	5.0–6.2	64	5.3	5.0–6.0	98	5.7	5.0–6.0	162
m12	5.7	5.0–6.3	153	5.7	5.0–6.3	227	5.7	5.0–6.3	380

TABLE 9 Adjusted coefficients for EYE-2 + sEIP vs. sEIP only for HoNOS hallucinations and delusions, subscale scores and overall score at m6, m9 and m12

	Adjusted coefficient (EYE-2 + sEIP vs. sEIP only)	95% CI	*p*-value
Hallucinations and delusions (range 0–4)			
m6	−0.08	−0.27 to 0.11	0.397
m9	0.11	−0.23 to 0.45	0.525
m12	0.05	−0.16 to 0.25	0.659
Behaviour (range 0–12)			
m6	0.14	−0.17 to 0.45	0.374
m9	0.00	−0.35 to 0.34	0.981
m12	0.05	−0.49 to 0.60	0.847
Impairment (range 0–8)			
m6	0.02	−0.20 to 0.23	0.884
m9	0.11	−0.28 to 0.50	0.591
m12	0.01	−0.24 to 0.26	0.948
Symptoms (range 0–12)			
m6	−0.05	−0.46 to 0.37	0.831
m9	0.51	−0.24 to 1.26	0.184
m12	0.05	−0.41 to 0.51	0.826
Social (range 0–16)			
m6	0.06	−0.41 to 0.54	0.796
m9	0.26	−0.58 to 1.11	0.542
m12	0.38	−0.13 to 0.89	0.140
Overall (range 0–48)			
m6	−0.27	−1.42 to 0.88	0.645
m9	1.31	−0.65 to 3.28	0.189
m12	0.88	−0.33 to 2.10	0.154

Deaths

Three (0.8%) participants died in the sEIP only arm before m12 and one (0.2%) died in the EYE-2 + sEIP arm. Four (0.4%) died overall in the first 12 months, with one further suicide occurring in the intervention arm during the follow-up.

National Institute for Health and Care Excellence guideline interventions

Table 13 summarises evidence derived from case notes of receipt of NICE guidelines interventions in the first 12 months with an EIP service. These data suggest that the median number of interventions received per participant was five in each arm and that medication, physical health assessments, CPA, vocational and family support were the most common approaches received, followed by CBT. The low proportions of patients in receipt of some of these interventions may have reflected delivery during COVID and that only the first 12 months of time with a service is captured.

TABLE 10 Adjusted coefficients for EYE-2 + sEIP vs. sEIP only for QPR score, and DIALOG QoL and TS scores at m3, m6, m9 and m12

	Adjusted coefficient (EYE-2 + sEIP vs. sEIP only)	95% CI	*p*-value
QPR (range 0–60)			
m0	0.00		
m3	0.83	−1.90 to 3.55	0.553
m6	0.30	−1.69 to 2.28	0.770
m9	−0.51	−3.16 to 2.15	0.707
m12	0.59	−1.37 to 2.55	0.554
DIALOG QoL (range 1–7)			
m0	0.00		
m3	0.14	−0.11 to 0.38	0.270
m6	0.01	−0.19 to 0.21	0.896
m9	−0.10	−0.40 to 0.20	0.513
m12	−0.06	−0.24 to 0.11	0.493
DIALOG TS (range 1–7)			
m0	0.00		
m3	0.12	−0.16 to 0.39	0.403
m6	−0.11	−0.33 to 0.10	0.310
m9	−0.22	−0.51 to 0.07	0.131
m12	0.00	−0.19 to 0.19	0.982

Additional analyses

Sensitivity analyses

Sensitivity analyses were performed to assess the effect of data collection methods (care co-ordinator collected data and RA collected data) on HoNOS scores and the effect of out-of-window data collection for HoNOS, QPR and DIALOG scores. The models were refitted using data under different conditions and compared to the results from the main models with all data included.

HoNOS models fitted with care co-ordinator data only produced results very similar to those produced by the main HoNOS models, indicating that the results for HoNOS were not affected by method of data collection.

For HoNOS, QPR and DIALOG models were fitted using in-window data only and compared to the main models with data reassigned to the closest time point. Despite the large amount of out-of-window data, results for the in-window data only models were very similar to the results from models fitted using all data, indicating that the results were not affected by collection windows.

Impact of the coronavirus-19 pandemic

To assess the impact of the COVID-19 pandemic, the models for disengagement, HoNOS, QPR and DIALOG were refitted using participants for whom baseline data were collected either before or after the date of the first lockdown. For disengagement, the participant's first assessment date was considered to be the baseline date. For QPR and DIALOG, participants without a baseline measurement were excluded from this sensitivity analysis. These models were compared with the results from the main models, and also combined using fixed-effects meta-analysis.

TABLE 11 Adjusted HoNOS scores at each time point and for each intervention arm

	sEIP only		EYE-2 + sEIP		Overall	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
Hallucinations and delusions (range 0–4)						
m0	2.26	2.19 to 2.34	2.26	2.19 to 2.34	2.26	2.19 to 2.34
m6	1.16	1.01 to 1.31	1.08	0.96 to 1.19	1.11	1.02 to 1.20
m9	1.28	1.04 to 1.53	1.31	1.12 to 1.50	1.30	1.15 to 1.45
m12	1.18	1.02 to 1.33	1.14	1.03 to 1.25	1.15	1.07 to 1.24
Behaviour (range 0–12)						
m0	2.61	2.47 to 2.75	2.61	2.47 to 2.75	2.61	2.47 to 2.75
m6	1.36	1.13 to 1.59	1.50	1.30 to 1.69	1.44	1.30 to 1.59
m9	1.41	1.02 to 1.81	1.60	1.28 to 1.92	1.53	1.28 to 1.78
m12	1.49	1.25 to 1.72	1.62	1.44 to 1.81	1.57	1.43 to 1.72
Impairment (range 0–8)						
m0	1.08	0.99 to 1.16	1.08	0.99 to 1.16	1.08	0.99 to 1.16
m6	1.04	0.87 to 1.20	1.05	0.92 to 1.18	1.05	0.94 to 1.15
m9	0.92	0.65 to 1.19	1.04	0.83 to 1.25	0.99	0.83 to 1.16
m12	1.06	0.90 to 1.22	1.08	0.96 to 1.20	1.07	0.98 to 1.17
Symptoms (range 0–12)						
m0	5.40	5.25 to 5.55	5.40	5.25 to 5.55	5.40	5.25 to 5.55
m6	1.04	0.87 to 1.20	1.05	0.92 to 1.18	1.05	0.94 to 1.15
m9	0.92	0.65 to 1.19	1.04	0.83 to 1.25	0.99	0.83 to 1.16
m12	1.06	0.90 to 1.22	1.08	0.96 to 1.20	1.07	0.98 to 1.17
Social (range 0–16)						
m0	3.97	3.78 to 4.17	3.97	3.78 to 4.17	3.97	3.78 to 4.17
m6	3.43	3.07 to 3.80	3.50	3.20 to 3.79	3.47	3.25 to 3.70
m9	3.36	2.77 to 3.95	3.68	3.22 to 4.15	3.56	3.19 to 3.92
m12	3.19	2.84 to 3.54	3.63	3.36 to 3.91	3.46	3.25 to 3.68
Overall (range 0–48)						
m0	13.02	12.63 to 13.41	13.02	12.63 to 13.41	13.02	12.63 to 13.41
m6	9.59	8.66 to 10.53	9.32	8.67 to 9.98	9.43	8.90 to 9.96
m9	8.85	7.51 to 10.19	9.89	8.82 to 10.97	9.49	8.66 to 10.32
m12	9.12	8.24 to 10.00	9.73	9.09 to 10.38	9.50	8.99 to 10.01

For disengagement, the pre- versus post-lockdown models were fitted for 660 participants (116 disengagements) pre and 345 participants (44 disengagements) post lockdown. This was the same number as fitted for the primary outcome model (1005 participants, 160 disengagements).

For the HoNOS subscales, the pre- versus post-lockdown models were fitted for the same number of participants as the main models. For overall HoNOS score, the pre- to post-lockdown models were fitted for 547 versus 204 participants, 751 in total.

TABLE 12 Adjusted QPR, DIALOG QoL and TS scores at each time point and for each intervention arm

	sEIP only		EYE-2 + sEIP		Overall	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
QPR (range 0–60)						
m0	37.20	35.83 to 38.56	37.20	35.83 to 38.56	37.20	35.83 to 38.56
m3	38.79	36.69 to 40.90	39.62	37.91 to 41.33	39.27	37.95 to 40.60
m6	40.22	38.76 to 41.69	40.52	39.11 to 41.92	40.40	39.35 to 41.44
m9	41.29	39.41 to 43.17	40.78	38.87 to 42.69	40.99	39.62 to 42.37
m12	42.42	40.95 to 43.88	43.01	41.69 to 44.33	42.76	41.77 to 43.75
QoL (range 1–7)						
m0	4.47	4.34 to 4.60	4.47	4.34 to 4.60	4.47	4.34 to 4.60
m3	4.67	4.47 to 4.86	4.80	4.66 to 4.95	4.75	4.63 to 4.86
m6	4.88	4.74 to 5.02	4.89	4.76 to 5.03	4.89	4.79 to 4.99
m9	4.98	4.74 to 5.22	4.88	4.69 to 5.07	4.92	4.77 to 5.07
m12	5.04	4.91 to 5.17	4.98	4.86 to 5.10	5.00	4.92 to 5.09
TS (range 1–7)						
m0	5.09	4.96 to 5.22	5.09	4.96 to 5.22	5.09	4.96 to 5.22
m3	5.24	5.01 to 5.47	5.36	5.20 to 5.51	5.31	5.18 to 5.44
m6	5.70	5.56 to 5.85	5.59	5.44 to 5.75	5.64	5.53 to 5.75
m9	5.62	5.42 to 5.82	5.40	5.19 to 5.61	5.49	5.35 to 5.64
m12	5.61	5.47 to 5.75	5.62	5.49 to 5.74	5.62	5.52 to 5.71

For QPR the pre- versus post-lockdown models were fitted for 400 versus 222 participants, 598 in total. The main analysis model was fitted for 775 participants.

For DIALOG QoL the pre- to post-lockdown models were fitted for 366 versus 221 participants, 598 in total. The main analysis model was fitted for 753. For DIALOG TS the pre- and post-lockdown models were fitted for 377 versus 214 participants, 591 in total. The main analysis model was fitted for 757 participants.

For all outcomes, the two models produced very similar results. Combining the results gave estimates very similar to those produced by the main analysis models, suggesting that the COVID-19 pandemic did not impact upon the study results. A limitation of this work however is that dichotomising participants either side of the first lockdown date is a very simplistic method to assess the effect of COVID-19 on outcomes, as all participants would have received between 12 and 16 months of EYE-2 or sEIP service delivery during COVID-19.

Subgroup analyses

The effect of the EYE-2 intervention on disengagement was assessed in several subgroups:

- substance misuse – binary 2, 3 or 4 versus 0 or 1 on HoNOS item 3
- symptom severity (HoNOS symptom score)
- ethnic group (mixed/other, any black, any Asian vs. any white)
- educational attainment (degree, vocational, A-level, GCSE vs. none)
- deprivation category (high vs. low)
- sex (male vs. female only)

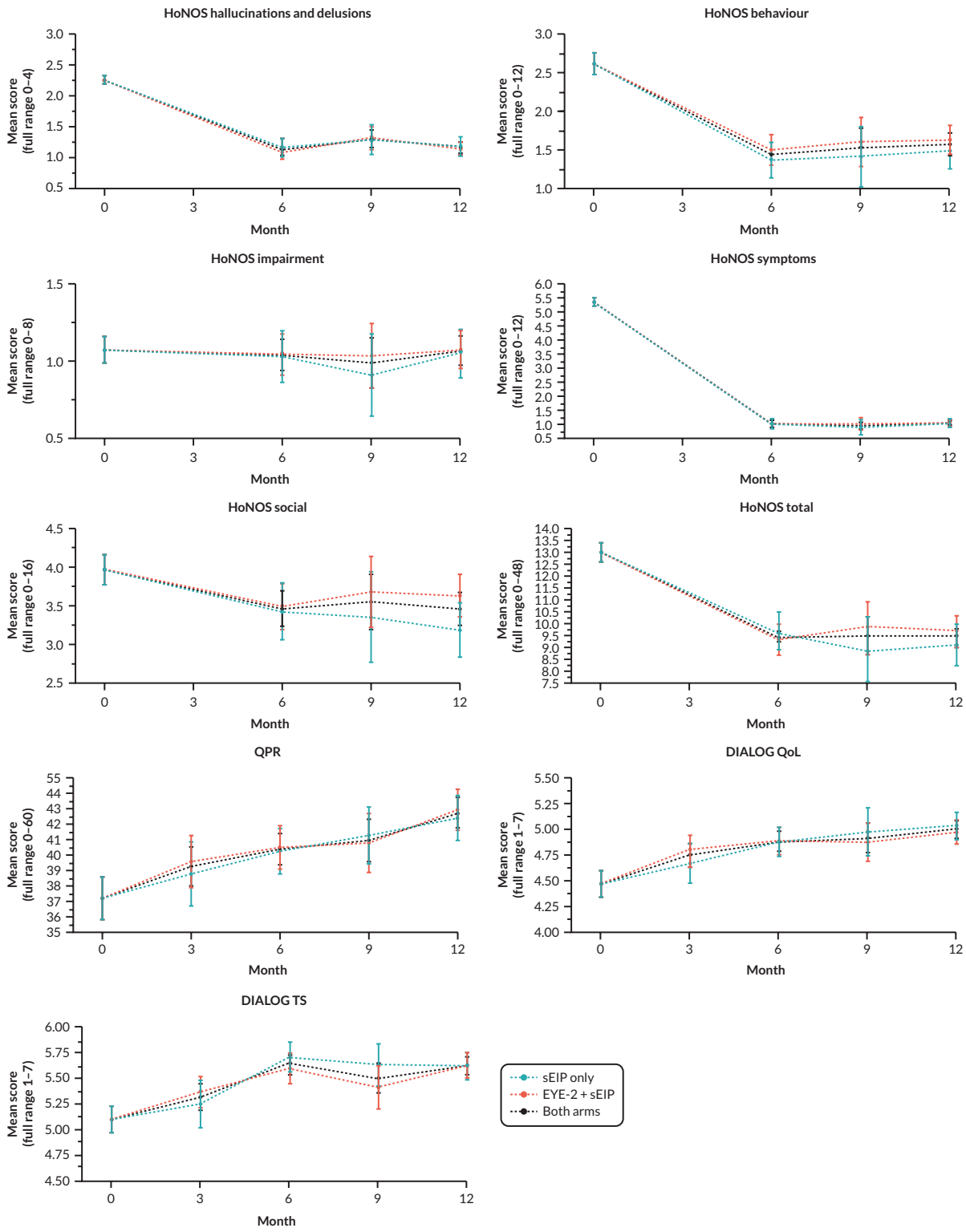

FIGURE 8 Visualisation of adjusted HoNOS, QPR and DIALOG scores at each time point and for each intervention arm.

Additionally for disengagement and HoNOS, QPR and DIALOG, in the following subgroups:

- average caseload per care co-ordinator in the team (high vs. low);
- funding level per team (high vs. low).

Subgroups were assessed by refitting the analysis models with the subgroup covariate and an interaction between intervention arm and subgroup to allow for different intervention effects within the subgroup.

TABLE 13 Summary of the number of NICE guideline interventions, by intervention arm

	sEIP only			EYE-2 + sEIP			Overall		
	Median	**IQR**	***n***	**Median**	**IQR**	***n***	**Median**	**IQR**	***n***
Number of NICE interventions up to m12	5.0	3.0–7.0	375	5.0	3.0–7.0	652	5.0	3.0–7.0	1027
	n	**%**		***n***	**%**		***n***	**%**	
Medication									
No	63	16.8		96	14.7		159	15.5	
Yes	312	83.2		556	85.3		868	84.5	
CBT									
No	291	77.6		509	78.1		800	77.9	
Yes	84	22.4		143	21.9		227	22.1	
Family support									
No	233	62.1		384	58.9		617	60.1	
Yes	142	37.9		268	41.1		410	39.9	
Family intervention									
No	337	89.9		557	85.4		894	87.0	
Yes	38	10.1		95	14.6		133	13.0	
Physical health assessment									
No	141	37.6		236	36.2		377	36.7	
Yes	234	62.4		416	63.8		650	63.3	
Physical health intervention									
No	340	90.7		572	87.7		912	88.8	
Yes	35	9.3		80	12.3		115	11.2	
Occupational/vocational intervention									
No	261	69.6		471	72.2		732	71.3	
Yes	114	30.4		181	27.8		295	28.7	
Peer support intervention									
No	358	95.5		614	94.2		972	94.6	
Yes	17	4.5		38	5.8		55	5.4	
CPA review									
No	113	30.1		172	26.4		285	27.8	
Yes	262	69.9		480	73.6		742	72.2	
Social groups									
No	333	88.8		591	90.6		924	90.0	
Yes	42	11.2		61	9.4		103	10.0	
Other									
No	364	97.1		568	87.1		932	90.7	
Yes	11	2.9		84	12.9		95	9.3	

Note
Individual interventions are listed for participants with at least one intervention.

Disengagement, Health of the Nation Outcome Scales, questionnaire on the process of recovery and DIALOG subgroup summaries.

There was no evidence for different intervention effects on disengagement between any of the subgroups and no evidence for an interaction between HoNOS symptoms score at baseline and intervention arm (which was included as a continuous variable rather than grouped).

There was no evidence for different intervention effects on HoNOS hallucinations and delusions, behaviour, impairment, symptoms, social subscale or overall scores, or DIALOG QoL or TS scores in the Low versus High average caseload groups.

There was weak evidence of a small difference between the EYE-2 + sEIP and sEIP only arms for QPR where the coefficient for the EYE-2 (95% CI) arm was −3.53 (−7.00 to −0.55, *p*-value: 0.046), suggesting that teams with low average caseloads in the EYE-2 + sEIP arm performed slightly less well at improving recovery than teams with low average caseloads in the sEIP only arm . However, this difference is small, and was the opposite of what might be expected in that both the EYE-2 intervention and lower caseloads should enable teams to improverecovery more effectively than the sEIP arms with similar case loads. This effect could therefore be a chance observation due to the number of models fitted and tests performed

Adverse events

No adverse events were recorded.

Fidelity

Fidelity to the Intervention was only relevant to the intervention arm and was analysed separately after all other analyses were completed. *Table 14* summarises fidelity score by team and overall. Overall median scores of 2–2.3 out of 4 revealed moderate implementation overall, which varied by team and over time. Fidelity decreased from early to late intervention in 83% of teams, and was lower than anticipated. Scores of 2–2.3 mean that clinicians who completed the survey were only using the resources with approximately half of their service users. In terms of good fidelity, we would have expected clinicians to have been using the resources with at least 75% of their service users: represented by a score of 3 or above. Only 7 of the 11 teams reported reaching any scores of 3 or more, and only 4 of these reported any scores at this level for more than one time point.

Analysis summary

There were no appreciable differences between the EYE-2 + sEIP arm and the sEIP only arm for disengagement, service use (nights in hospital/A&E presentations/Section 136 use), HoNOS, QPR, DIALOG, deaths or NICE guideline interventions use. Visual summaries of the results are provided in *Figures 9* and *10*.

For HoNOS, QPR and DIALOG, results were not substantially affected by use of only data collected in window, collected by care co-ordinators only, or for participants with baseline data collected before or after the start of the first COVID lockdown (23 March 2020).

Subgroup analysis did not identify any differential intervention effects within subgroups, except for weak evidence for less improvement in QPR score for the EYE-2 + sEIP arm in the low average caseload group, compared to the sEIP alone arm.

Discussion

Summary of the results

Study strengths and value

This project has produced valuable insights, revealing for the first time, the pattern of disengagement, health outcomes, QoL and service use in a total sample population of all patients aged 14–35 meeting criteria for a first episode of psychosis presenting over a 12–14-month period, with follow-up over 12–26 months, in 20 teams, across 9 NHS Trusts

TABLE 14 Intervention fidelity scores by team and overall

		T1	T2	T3
N1	Median	2.7	1.9	2.3
	IQR	1.5–2.8	1.3–2.6	1.0–2.8
	n	3	4	4
N2	Median	1.0	1.6	1.8
	IQR	1.0–1.0	1.0–2.3	0.4–3.0
	n	1	7	9
H1	Median		2.4	2.3
	IQR		1.7–2.5	2.1–3.7
	n	0	4	3
H2	Median	3.0	1.5	2.8
	IQR	2.0–3.8	1.3–1.8	1.5–4.0
	n	7	2	2
L1	Median	1.3	1.0	0.5
	IQR	1.3–1.8	1.0–1.0	0.0–1.0
	n	5	2	2
L2	Median	1.8	2.3	1.6
	IQR	1.7–3.0	2.0–2.6	0.2–3.0
	n	3	4	2
L3	Median	2.2	2.2	1.4
	IQR	1.8–2.8	1.7–2.3	0.3–2.4
	n	6	3	2
M1	Median	1.6	1.9	1.5
	IQR	1.0–2.0	1.0–2.8	1.2–1.9
	n	3	2	2
M2	Median	2.4	1.4	1.9
	IQR	2.3–2.5	1.4–1.4	1.3–2.5
	n	2	1	2
M3	Median	3.7	3.1	2.3
	IQR	3.7–3.7	3.1–3.1	2.3–2.3
	n	1	1	1
TV1	Median	2.5	2.8	2.2
	IQR	2.4–3.0	1.0–3.3	1.3–2.8
	n	3	10	7
TV2	Median	2.4	2.0	1.7
	IQR	2.0–2.8	1.8–3.0	0.3–2.8
	n	8	6	7

TABLE 14 Intervention fidelity scores by team and overall (*continued*)

		T1	T2	T3
Overall	Median	2.3	2.1	2.0
	IQR	1.8–2.9	1.3–2.8	1.0–2.8
	n	42	46	43

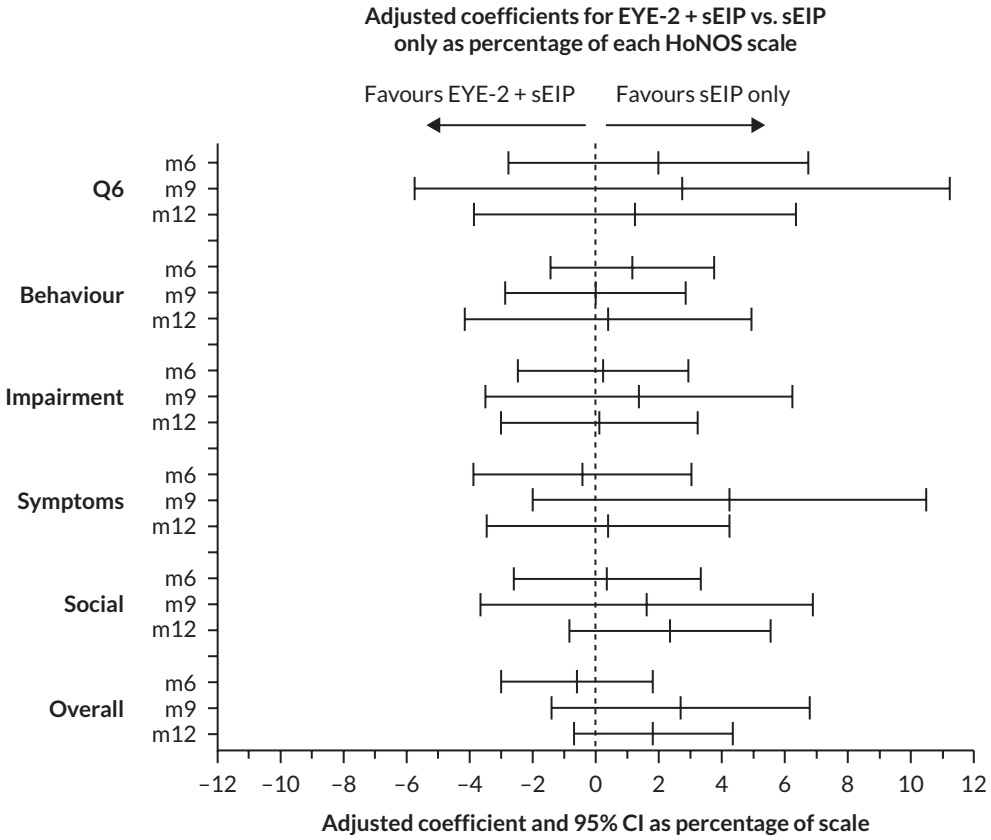

FIGURE 9 Visualisation of adjusted coefficients for EYE-2 + sEIP vs. sEIP only for HoNOS hallucinations and delusions (Q6), subscale scores and overall score at 6, 9 and 12 months, as a percentage of each scale.

in England, including rural, urban, North and South locations. This sample is thus representative, and demographics and outcomes are generalisable to the whole population of new FEP service users in England, as the sample comprises approximately 10% of all new first-episode patients in England in a 14-month period. Disengagement was rigorously defined with reference to a detailed protocol. Engagement status was double-rated blind to study arm, by a RA and a clinical psychologist, with high concordance. Time to disengagement data was available for all participants and was censored for those who were lost to follow-up: complete data were available for 100% of the primary outcome for this total population sample.

Randomisation was stratified by site. However, in one site, two teams were co-located, sharing office space and delivering groups together. They were combined for randomisation purposes to create three large teams, two of which were then randomised to the intervention arm. In a second site, three out of five teams were randomised to the intervention arm. This led to 11 teams and 652 participants in the intervention arm and 9 teams and 375 participants in the sEIP only arm. A comparison of demographic and clinical characteristics, nevertheless, revealed that participants were exceptionally well-balanced across arms. Mean age was 25.1 years, 63.1% identified as male, 51.8% were White

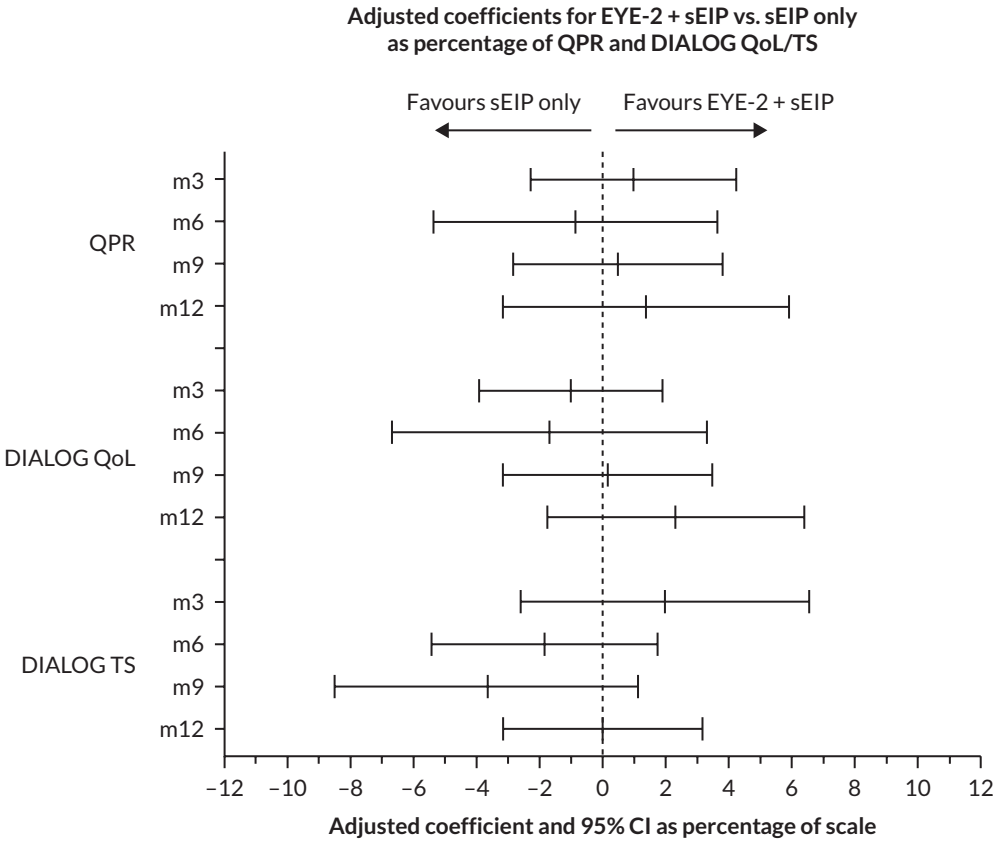

FIGURE 10 Visualisation of adjusted coefficients for EYE-2 + sEIP vs. sEIP only for recovery (QPR), subjective QoL (DIALOG) and TS (DIALOG) score at 6, 9 and 12 months as a percentage of each scale.

British or other white background, 70.2 % were living in areas of below average deprivation at onset, 57% were educated to A levels or above.

Primary disengagement outcome

The primary analysis revealed that contrary to our hypotheses, there were no differences between time to disengagement in our EYE-2 intervention arm plus sEIP and sEIP alone. Moreover, the proportion of young people who disengaged was much lower than expected based on previous meta-analyses (25–30%),[34,47] at 16% in both arms of the study. In itself, this is a positive finding in that both arms of the study had comparatively low disengagement. There were minimal clustering effects and so no substantial variation in rate across teams.

Loss to follow-up

Twenty-one per cent of young people were lost to follow-up. These data are important as they emphasise the transience and instability of this population of young people, many of whom moved or where already living, out of area, or abroad. Many were away from home when they became unwell and simply returned home, while others moved away after becoming unwell. This is clinically important considering the well-documented role of migration, regional discrimination including in displaced white populations, and ethnic density, and the potential impact of reduced social networks and support on the incidence of psychosis.[121,122]

Secondary health, recovery and quality of life outcomes

Our secondary analyses revealed no effects of the intervention on secondary health, recovery, QoL or TS outcomes. Reductions in HoNOS total score, social, behavioural, and symptom subscale scores, and the hallucinations and delusions score, were similar in participants receiving the intervention and those receiving sEIP alone, with most change occurring in the first 6 months. Scores were highest at baseline for the hallucinations and delusions, and symptom scores, and low for other subscales; the total score had medians of 12 and 14 out of 48. On the QPR, median scores were 39 and 41 at baseline, rising to 44 and 43 at 12 months, with similar improvements over time in both arms.

Baseline scores were close to the mean score of 38.7 reported for 399 older patients with longer-term psychosis, but scores at 12-month follow-up revealed greater recovery for this younger sample.[123] Likewise, on the DIALOG, baseline subjective QoL scores were 4.5 and 4.6, rising to 5.1 and 5 at 12-months, while TS scores started at 5 and 5.2, rising to 5.7 at 12 months. Baseline scores started lower than those reported by Priebe *et al.* (4.8 for subjective QoL; 5.5 for TS),[124] for 271 older patients with schizophrenia spectrum diagnoses but quickly surpassed these scores to stabilise at 6 months.

Initial service use outcomes

There was evidence of receipt of a median of five NICE guidelines interventions by service users during the first 12 months of the project in each arm of the study. Twenty per cent of patients in each arm had at least one A&E contact, and 42% had at least one hospital admission. The odds of at least one A&E contact and the incidence of nights spent in hospital were both slightly lower in the EYE-2 arm. This will be explored further in *Chapter 6*.

Deaths

At the design stage, lived experience advisors were interested in the potential for the intervention to reduce death due to suicide. Unfortunately, four young people died due to suicide during the trial, and one died from other causes, but suicide levels were very low levels in both arms (0.5% in sEIP and 0.3% in EYE-2).

Subgroup and sensitivity analyses

Subgroup and sensitivity analyses confirmed that the results were not impacted when the results were restricted to only secondary data collected within prespecified windows, or only HoNOS data collected in the standard way or only data collected for people allocated before versus after the first lockdown. The effect of the intervention on disengagement did not differ in subgroups varying in substance use, symptoms at baseline, ethnicity, education, deprivation or gender. There was a slight tendency for lower recovery in EYE-2 intervention teams with smaller caseloads, but this was the opposite of what might be expected with EYE-2 or lower caseloads as defined by EIP guidelines[125] and seems likely to be a chance finding due to multiple comparisons.

Explanations for lower-than-expected disengagement rates and lack of difference between standardised Early Intervention in Psychosis service and the Early Youth Engagement-2 intervention

Team selection

Teams were specifically selected to be standardised high-quality EIP teams, with regional support, and an identified local investigator with a strong academic track record in leading trials in psychosis. It is possible that all teams performed better than the average team in the UK in promoting engagement.

Short follow-up duration

It is possible that the planned shorter follow-up for those who entered the study later led to lower observed disengagement rates. The 25–30% rate reported by Doyle *et al.* was over 12–24 months,[34] and while our own EYE study revealed a disengagement rate of 24% at 12 months,[47] our own updated review revealed that the median time to disengagement was 15 months.[126] Disengagement rates may have been higher and greater difference revealed with a 24-month follow-up for all patients.

Stringency of disengagement definition

It is possible that our definition of disengagement was more stringent than previous studies, requiring that patients were first assessed and allocated to a care co-ordinator before entering the study, and that they met clear disengagement criteria, further reducing rates and differences in disengagement.

Influences linked to National Health Service England Access and Waiting Time Standards

Improved Early Intervention in Psychosis service provision

Disengagement rates may be lower in the UK since the introduction of the AWTS in 2016. The Doyle *et al.*[34] systematic review used data only to 2013, and the EYE project completed in 2015.

There has been significant investment in EIP staffing since 2016, to enable teams to offer a NICE guidelines concordant service provision within 2 weeks of first presentation to services.[33,55] It is therefore entirely possible that since 2016, service users have received better-quality services, with greater choice of treatment options in both arms of the study: the median NICE recommended interventions received was five in both arms. This overlapped the focus of the EYE-2 to offer treatment choices; hence, although the EYE-2 intervention may provide clinicians and service users with resources that back up treatment offers, it may not have enhanced service quality or expanded the breadth of treatments offered beyond that which was enabled by the funding increase.

Increased caseload demands and stringency in acceptance

Two new requirements, to allocate all new FEP patients to a care co-ordinator within 2 weeks of first presentation to NHS services, and to extend EIP services to include also new first-episode patients aged 36–65, may have substantially increased demands on services, which then responded with increasingly stringent entry criteria to manage demands. There is some evidence for this, as numbers of new patients aged 14–35 were substantially lower in many teams, than had occurred in previous years, and qualitative data revealed increased stringency in acceptance onto caseload to manage demands (see *Chapter 7*). The impact of this may be that the EIP caseload has changed to include fewer patients with diagnostic uncertainty, and more patients with schizophrenia spectrum diagnoses, who due to poorer mental health are more pro-actively engaged and are not 'allowed' to disengage.

Training and support in robust and meaningful outcome data as an active intervention

Access and Waiting Time Standards also came with a new expectation to collect routine outcome measures in standard EIP services. New targets were introduced in the National Clinical Audit of Psychosis (NCAP)[127] for services to collect 'paired outcomes' (baseline and follow-up within 12 months) on at least two questionnaires from HoNOS, QPR and DIALOG. The percentage of patients in an EIP service with paired outcomes was taken as an indicator that a service was 'well-managed' and services were encouraged to aim for at least two questionnaires, collected twice for at least 50% of service users.

Alongside this, the EYE-2 study aimed to use these routine outcome measures to evaluate the intervention in both arms. Prior to the start of the EYE-2 project in July 2017, questionnaire data were available for at least one outcome for 22% of patients, but completion rates varied widely with some teams already collecting paired outcomes for up to 75% of patients, and some having no data. The EYE-2 team developed, piloted and delivered a half-day manualised training in outcome data collection to over 80% of all staff in all teams involved in the study. The data collection training and manual (see *Project document 1*) focused on ensuring the collection of clinically meaningful outcomes to identify a young persons' goals (a key part also of the EYE-2 approach) and inform treatment planning and intervention approaches. Our training was adopted by NHS-E/I and formed the basis of training webinars and an e-learning programme on collecting outcome data.[128] Patients were involved in delivering the training to make it more meaningful; colourful, user-friendly measures packs were developed to make the task easier; outcome measures reports for service users and clinicians, were developed with input from our LEAPs (see *Chapter 2*) and used to encourage data collection. 'Within-team' RAs in both arms, sent regular reminders to care co-ordinators to collect data, and helped teams by collecting data themselves. Some staff clearly viewed the outcome measure collection as a key part of the EYE-2 intervention (see *Chapter 7*). One clinician for example told us: 'we're using QPR and dialogue as part of the [EYE-2] approach'. It is therefore entirely possible that the NHS-E targets, combined with the EYE-2 data collection training and embedded team support, inadvertently constituted an intervention in its own right, encouraging staff to listen and focus on the recovery needs, QoL and treatment goals of their patients, which in turn had a direct impact on reduced disengagement in both arms of the study.

The impact of coronavirus disease-19 on engagement and disengagement, and intervention delivery

Finally, it is possible that the pattern of disengagement and intervention delivery were influenced by the COVID-19 pandemic and were more turbulent and less predictable than expected. Our sensitivity analysis found no evidence for this but was based solely on comparing outcomes in those with baselines collected before or after the first lockdown. In reality, every patient and every team were impacted by the pandemic. Only the first 10 months of the trial were pre COVID-19, and there was no pause in the trial due to COVID-19, as the trial was a total population cohort and

teams, and patients were already enrolled. The remaining 16 months of the trial ran during COVID-19. During this time, there was great upheaval with threat of closure of EIP services, high staff sickness, staff stress, staff redeployment, reduced or no F2F contact, high levels of remote and home working, a new era of VC, and use of personal protective equipment (PPE; masks, gowns, gloves and visors) in F2F contacts.[129–131] All these factors may have created barriers that increased disengagement.

At the same time, multiple lockdowns made it harder to leave the home or local environment without risk of prosecution, and easier to engage with services by simply responding to a phone call with no requirement to travel or meet F2F. Frequency of contacts also reduced, and while for some people this was challenging, for others this light touch was preferred and served to enhance engagement.[132] Mental health problems became normalised and were openly discussed as a response to the pandemic, and families and communities also rallied to support those in need, potentially aiding with practical tasks and providing social support which is a further key component of EYE-2, known to promote engagement.[47,126] All these factors may have served to enhance engagement. Hence, rates and processes of both engagement and disengagement became more unpredictable, and variable across time, and by site, as local lockdowns, and allocation to 'Tiers' dependent on local virus levels became the norm.[133]

In terms of fidelity, the scores provided by clinicians indicated that of those clinicians who reported their fidelity, few were consistently using the resources with more than half of their patients. For the intervention to be effective, we would expect clinicians to be using the resources with most, or all of their patients, but this only happened in some teams and only at some time points. The pandemic may also have impacted implementation of the EYE-2 intervention, across sites, contributing to the fact that delivery was not as planned, and fidelity was low. Certainly, while fidelity scores showed variation in implementation across team, there was also a reduction in implementation over time post COVID-19. This was especially likely for the component of social support, as contact with family, friends and peer run social groups were all impacted. These factors are considered in *Chapter 7*.

Elucidating the greatest impacts on disengagement

Two sets of evidence can shed light on the veracity of these hypotheses. Using data published internationally between 2010 and 2020, our recent systematic review and meta-analysis revealed highly heterogeneous rates of disengagement from FEP services, ranging from 1% to 41%, impacted by definition of disengagement, follow-up duration and year of publication, with higher rates in earlier studies internationally. Nine looked at time to disengagement, five of these using the same Kaplan–Meier curves as used in our current study and reported times to disengagement between 5 and 22.5 months, with a median of 15 months. This study followed people up for a minimum of 12 and a maximum of 26 months, which means that some but not all participants would have passed at least the median time to disengagement reported internationally. Only one study from the review[134] was based in the UK and on data up to 2013, and this revealed a rate of disengagement of 11.7% at 3 years. Hence, disengagement rates are markedly impacted by definition, and have been reducing internationally over time, possibly linked to better service models and more rigorous evaluation. Our rate of disengagement of 16% in both arms, while substantially lower than previously published data,[34] is in fact consistent with the pooled disengagement rate internationally of 15.6%.[126] The stringency of our disengagement definition and the length of follow-up may both have contributed to our lower disengagement rates.

Secondly, qualitative and quantitative data from our process evaluation (see *Chapter 7*) can tell us more about the impact of the AWTS, service provision, acceptance patterns, the EYE-2 outcome measures training, and COVID-19 on disengagement.

Staff turnover and data collection processes

Insufficient training and staff turnover

It is possible that the intervention is effective, but that staff were insufficiently trained and supported to deliver it. Over 80% of staff were trained initially, and booster trainings were offered 6-monthly, but there was high staff turnover in some sites, training moved online during the second booster training and all subsequent training was delivered remotely. This is explored further in *Chapter 7*.

Sensitivity of measures to change or to administration

It is possible that the outcome measures were insufficiently sensitive to change, or that clinicians at least for the HoNOS, were insufficiently trained to administer and rate these outcomes sensitively. However, outcome measures were selected because they are NHS-England-mandated outcomes for use in EIP services nationally, they have psychometric data showing sensitivity to change, reliability and validity.[123,124] Staff were provided with a half-day training in collecting the outcome measures reliably and robustly and were reminded of the importance of data collection in all 6-monthly booster trainings. All measures did show change over time in the study.

Baseline secondary outcome data may also have been collected too late following first presentation to capture the lowest point of health, recovery and QoL, thus may have missed some of the change in outcome from first episode. Even for the HoNOS, where the majority (85%) of baseline data were collected within 6 weeks of allocation to care co-ordinator, scores were within the lowest 25–50% of scores, thus potentially limiting the ability to detect change. The exception to this was the symptom scores which were higher. Patient-reported outcome data were even more impacted where fewer than 50% of data were collected in the first 6 weeks of service use. One clinician told us:

> *I don't do DIALOG in the initial assessment Um, I wait until they've actually been with the team for like, they've actually started the medication, they've actually . . . had a fair chance to answer those questions.*

Although QPR and DIALOG data did change from baseline to month 3 and 6, it is unclear whether initial scores would have been lower or change greater if data were collected at or close to first presentation. This factor is likely to have impacted both arms similarly, however, and is unlikely to explain the results, where other aspects of data collection may have impacted.

Impact of high loss to follow-up on secondary outcome data collection

Rates for loss to follow-up were very high, comprising 21% of the total sample (15% at 12 months). Follow-up was not possible as they were no longer receiving the intervention as planned and this had major implications for data collection as the available sample was reduced considerably.

Impact of disengagement and coronavirus disease-19 on secondary outcome data collection

However, perhaps the greatest issue was the impact of disengagement on secondary outcome data collection. Our protocol included plans for collecting follow-up data for patients who had disengaged, including procedures for collecting the HoNOS and other data by telephone (see *Chapter 2*). However, this proved exceptionally challenging, exacerbated by the complexities of contacting people for the first time, to consent to take part in EIP research, once they had already disengaged, and during a national pandemic. Data completion was 98%, 83% and 65% for HoNOS at baseline, 6 and 12 months, respectively, with 80% completion for available patients at 12 months, and 58–61%, 42–44% and 35–36% at baseline, 6 and 12 months, respectively, with 50–51% completion for available patients at 12 months. However, for the 163 patients who disengaged, HoNOS, and QPR/DIALOG data were missing at 6 months for 28%, 35% and at 12 months for 58% and 67%. This means that with the exception perhaps of HoNOS at 6 months, there were insufficient data to reliably detect any differential impact of the intervention on mental health, recovery or well-being in patients who had disengaged.

No effect of a team-based whole population intervention

Finally, it also remains possible that the EYE-2 intervention, even when delivered optimally, is simply not effective at reducing disengagement. The team-based care co-ordinator-led approach may be ineffective; a finding not inconsistent with other care co-ordinator inventions in secondary mental healthcare services for people with psychosis and severe mental illness.[135,136] Alternatively, the intervention may be effective, but not when targeted at the whole population, which is also an outcome found recently for whole population mental health approaches.[137] It is possible that a targeted approach directed at those who are at greatest risk of disengagement, by more highly trained staff, might have had a better outcome. This will be explored in *Chapter 7*.

Limitations

There were several limitations to this study. Predictions were based on published rates of disengagement, but our own new evidence[126] suggests that these rates have recently changed such that both arms reached close to the original

target for the intervention arm of 15% disengagement. Loss to follow-up was much higher than anticipated and this led to a reduction in available follow-up data. Secondary outcomes, despite sustained efforts from the research team, were impacted by staff ability to collect the data, especially for people who were disengaging, and further exacerbated by the move to remote working with COVID-19. Use of routine data was nevertheless necessitated in order to explore mental health, recovery and QoL in people with poor engagement who were unlikely to consent to a research trial. Some data for the HoNOS were collected using non-standard interview, and case note screen methods, to maximise data completeness, necessitated by both disengagement and the pandemic. However, there was no evidence that this impacted the results. For patient-reported outcomes (QPR/DIALOG), first data collection was often delayed from baseline, potentially missing the poorest initial presentations, and reducing sensitivity to change. Further differential impact of disengagement on the collection of outcomes substantially limited the opportunity to detect an effect of the intervention on mental health and recovery post disengagement. Although the maximum follow-up period was 26 months, by design, follow-up ranged from 12 to 26 months. This meant that for some patients, follow-up duration may have been insufficient to capture disengagement.[126] Furthermore, although secondary data were collected up to 24 months for those who entered the study first, the sparsity of this data beyond 12 months meant that these data were not included in the final analysis of secondary outcomes. Finally, the COVID-19 pandemic itself contributed additional limitations as unprecedented turbulence and change in EIP teams and life across the country undoubtedly impacted on engagement practices and on the delivery of the intervention.

Conclusions

In a total population sample of 1027 young people presenting with a FEP and receiving good-quality standardised Early Intervention services in England, disengagement over a 12–26-month period was 16%, and did not differ for those who also received the EYE-2 intervention. Twenty-one per cent of the sample were lost to follow-up, many of whom were living away from home or moved away from home on or after onset. This is clinically important given that so many young people struggle with challenges due to migration, discrimination, and social isolation prior to the onset of psychosis, and highlights the need for more to be done to support young people living away from home.

Participants in both arms of the study demonstrated equivalent improvements in health, recovery and QoL outcomes, largely in the first 6 months, while consistent with the concept of recovery as a process,[138,139] recovery continued to improve over at least 12 months and surpassed levels seen in those with longer term illness.

There is no evidence that COVID, substance use, symptoms, education, ethnicity, deprivation or caseload size affect findings. Potential explanations for the absence of effect on outcomes include high-quality teams with improved EIP service provision in both arms, short follow-up duration, stringency of disengagement definition, and stringency of FEP definition so that those taken on are less well and followed up more assertively. High staff turnover and processes of data collection may also have played a part. The EYE-2 project worked alongside the AWTS, supporting the implementation of goal-focused outcome data collection, which may also have enhanced engagement experiences for those accepted onto EIP caseloads. COVID-19 undoubtedly led to less predictable patterns of engagement and disengagement. Finally, the team-based whole population approach may have been ineffective, and a more targeted approach might have better outcomes.

Chapter 6 Objective 5: the Early Youth Engagement-2 health economic evaluation

Aims and objectives

The aims of the health economic analysis were: to quantify the impact of the EYE-2 intervention on the cost of service contacts (NHS mental healthcare and wider care system costs) and clinical and social outcomes over a 12-month period; to evaluate the cost-effectiveness of the intervention from an NHS mental health system perspective; and to investigate the potential resource implications of the intervention for NHS mental health commissioners with a view to informing guidance on commissioning choices.

The study objectives were:

1. To estimate the difference in average mental health system costs (costs of planned and unplanned care contacts plus intervention cost) over a 12-month follow-up for study participants exposed to the intervention plus sEIP compared to sEIP only.
2. To identify the joint effect of the intervention on total NHS mental health system costs and clinical outcomes to determine whether: the intervention was the 'dominant' clinical strategy in cost-effectiveness terms compared to sEIP (i.e. whether EYE-2 was associated with lower total mental health system costs and superior clinical outcome); or whether sEIP was the dominant alternative; or the intervention involved a degree of trade-off between cost and clinical outcome compared to sEIP.
3. To estimate the effect of the intervention on wider care system costs (i.e. costs of service contacts outside of the mental health system) and whether the intervention was associated with higher or reduced overall 'societal' costs (a combination of total mental health system costs combined with wider care system costs).
4. To evaluate the effect of the intervention on measures of social outcome, specifically: days spent in stable and independent living arrangements; in employment (paid or unpaid); and undergoing education and training.
5. To determine whether there were differences in the likelihood of intervention compared to sEIP patients transitioning into different pre-defined clinical need-related mental health clusters (MHCs)[140] designed for care planning and provider cost re-imbursement.[141]

Methods

The analysis drew on cost analyses to evaluate the resource effect of the intervention; and cost-effectiveness analysis to consider its joint effect on mental health system costs and clinical outcome. All economic analyses were carried out on participant-level data and according to an ITT principle, though in analyses of social outcomes and wider care system costs a strict ITT approach was limited by substantial loss to follow-up. This trial was unusual in that all data except social and wider care cost data were collated without individual consent, so 'loss to follow-up' here refers to patients who were not contactable or declined consent to take part in an interview when contacted. The comparator comprised sEIP teams without the EYE-2 intervention. All analyses were 'within trial', based on measurements of service contacts and outcomes made at or over the 12-month period of follow-up from the point of allocation of a service user to a care co-ordinator in a trial team. The trial population and service context and setting are described elsewhere in the report.

Cost analyses were undertaken from varying perspectives. Evaluations of the effect of the intervention on the cost of planned and unplanned mental health service contacts and intervention costs were undertaken from an NHS mental healthcare provider perspective, as was the accompanying cost-effectiveness analysis: this was deemed appropriate as it was anticipated that most of the resource impacts of the intervention would be concentrated within the mental health system, for example by increasing contacts with EIP service professionals (through improved rates of service engagement) and through preventing the need for unplanned care contacts including admissions to psychiatric inpatient wards. A societal perspective was also adopted to analyse the effects of the intervention on wider care system costs as Early Intervention in Psychosis service users are likely to utilise a broad package of services within and outside

of the NHS depending on the type and complexity of needs. Wider system (or 'societal') impacts included cost of contact with non-psychiatric NHS hospital and community-based services; contact with non-NHS community-based services (inclusive of time spent in staffed accommodation) and contact with the police. The study did not consider costs of education and training activity, criminal justice costs beyond police contacts or resource and other outcomes for carers, including families of service users. All costs are reported at 2021–2 price levels. Discounting to adjust for the differential timing of costs estimated over follow-up was not deemed appropriate as measurement was restricted to a 12-month follow-up period. The report has been written with reference to the Consolidated Health Economic Evaluation Reporting Standards.[142]

Service contact measurement

Participant contacts with NHS mental health services were obtained from electronic case records held by participating EIP services. This covered all contacts made with mental healthcare professionals within EIP teams, all other community and outpatient NHS mental service contacts (whether planned or emergency) and psychiatric inpatient bed-day utilisation. Case note data were extracted by site RAs and entered using a study proforma (see *Project document 7*) to record volume of service contacts and other data for two 6-month periods making up the 12-month period of follow-up. The form was piloted in five sets of case notes at each site and feedback obtained to streamline and facilitate the process of data collection.

Wider (non-mental health system) service utilisation was measured using an adapted version of the patient self-report adult service use schedule (AD-SUS;[143] see *Project document 8*). The AD-SUS was administered 12 months post allocation to a care co-ordinator in an EIP team, by the blinded RAs (in most cases by telephone contact). Service users were first contacted by the 'within team' RA to check for willingness to be contacted about the study. Attempts to contact were made by telephone, letter and text. All interested respondents who subsequently consented were interviewed blind to study arm. Respondents were asked to report the frequency of contact made with a range of hospital and community-based services during the previous 12 months. To mitigate the risk of recall bias, an event timeline (timeline follow-back procedure) was employed during administration of the AD-SUS which gave respondents the opportunity to anchor their recall of service utilisation to key events over the previous 12 months (e.g. birthdays, holidays).

Early Youth Engagement-2 training activity and other intervention costs

To facilitate estimation of intervention costs each trial site provided a record of time allocated by training facilitators, PPI representatives and EIP team leads and care co-ordinators to intervention training activity. Financial expenditures on training event room hire and catering, intervention website development and costs of developing and producing intervention manuals and booklets were also provided and included as a cost of intervention implementation. Substantial 'one-off' expenditure on website development was converted to an annual equivalent (through annuitisation), assuming a 5-year lifetime for the website and a discount rate of 3%. EYE-2 social group contacts facilitated by PPI staff were not recorded in case notes and so were not costed as part of EIP delivery. Based on anticipated frequency, length and attendance at social group activity, the cost of social group contacts was expected to be low and unlikely to impact conclusions.

Costing service utilisation and professional time input

Contacts with services, staff and time allocated to intervention training activity were costed using appropriate unit costs values derived from national NHS Reference Costs[141] the Unit Costs of Health and Social Care[144] or other published sources (see *Appendix 6*, *Table 43*). The appropriate Agenda for Change pay bands were used with further adjustment for staff overheads and salary 'on-costs' as detailed in the Unit Costs of Health and Social Care[144] to facilitate an estimate of the full economic cost of time allocated to service contacts and other intervention activity.

Estimation of cost per trial participant

For each service item, the cost per participant was calculated as the total 'units' of service use multiplied by the respective unit cost. The intervention cost per participant was estimated by dividing total intervention costs by the number of trial participants in the intervention arm of the trial. For each trial participant, costs were then aggregated into broader categories defined in *Table 15*. As recommended by our GP commissioner, NHS costs were divided into planned and unplanned costs.

TABLE 15 Definitions of aggregated cost categories

Category of cost	Definition
From case note data	
Planned mental health care	Contact with EIP service professionals + medication usage
Unplanned (emergency) mental health care	Psychiatric bed-days + psychiatric A&E contacts + crisis team contacts + ambulance usage + Mental Health Act assessment + Section 136 suite usage
Total mental health system cost	Planned MHC cost + unplanned MHC cost + intervention cost
From participant self-report (AD-SUS) data	
Non-psychiatric NHS service contacts	Non-psychiatric inpatient bed-days + outpatient visits + A&E contacts + GP contacts + primary care nurse contacts + NHS direct + NHS helpline + NHS walk-in
Non-NHS community-based service contacts	Days in staffed accommodation + day centre visits + drop-in centre visits + social worker contacts + employment advisor contacts + housing officer contacts + benefit advisor contacts + citizen advisor contacts + psychiatrist contacts (non-NHS) + psychotherapist contacts (non-NHS) + counsellor contacts (non-NHS)
Police contacts	Arrests + other police contacts (e.g. victim of crime)
Wider system cost	Non-psychiatric NHS service contacts + non-NHS community-based service contacts + police contacts
Total societal cost	Total wider system cost + Total mental health system cost

Additional outcomes for health economic analysis

Clinical and social outcomes

Clinical outcomes were based on total scores extracted from the HoNOS[64] at 12 months post allocation.

Social outcome over the 12-month follow-up period was evaluated across three areas: number of days spent in independent and stable living arrangements (defined as any time *not* living in a hostel/refuge, temporary living arrangements, sleeping rough or in staffed accommodation); number of days in paid or unpaid work (full or part time); and number of days in training and education. These outcomes were selected as having wider policy relevance to the EIP age group. Measurement of each outcome was based on participant responses to questions embedded in the service contact questionnaire at 12-month follow-up.

Mental health clusters

The Royal College of Psychiatrists Mental Health Clustering Tool identifies 21 MHCs according to the presenting symptomology and clinical needs of a service user determined using the HoNOS and the Summary of Assessments of Risk and Need (SARN).[145] these are listed in *Table 16* along with the national NHS tariff linked to each (for the year 2020–1). All service users entering an EIP service began in cluster 10 (FEP). The clustering tool uses HoNOS item scores (items 1–13) and 5 SARN items (labelled 'A' through 'E') measuring historical problems occurring episodically, to allocate to MHC. A pre-existing algorithm[146] was used, incorporating empirically estimated weights that identify the relative importance of individual items in grouping service users within specific MHCs. The weights determine the probability that a study participant's observed clinical characteristics are indicative of membership in each possible MHC. The participant is allocated to the cluster with the highest probability value.

To simplify the analysis of participant MHC membership at follow-up we created 3 'overarching clusters' that grouped specific clusters under one of three headings: 'low cost' (clusters 11 and 12); 'moderate cost' (clusters 10, 13, 16 and 17) and 'high cost' (clusters 14 and 15) informed by their expected cost implications as indicated by the respective NHS daily tariffs (see *Table 16*).

TABLE 16 Mental health clusters and tariffs

	Description	NHS Reference Cost daily tariff (2021–2 price levels) (£)
'Low cost'		
Cluster 11	Ongoing recurrent psychosis (low symptoms)	24.48
Cluster 12	Ongoing recurrent psychosis (high disability)	36.60
'Moderate cost'		
Cluster 10	FEP	43.89
Cluster 13	Ongoing recurrent psychosis (high symptom and high disability)	73.80
Cluster 16	Dual diagnosis	61.04
Cluster 17	Psychosis and affective disorder (difficult to engage)	56.33
'High cost'		
Cluster 14	Psychotic crisis	172.86
Cluster 15	Severe psychotic depression	132.71

Statistical modelling

Differences in cost and clinical or social outcome between participants in the intervention and sEIP arms of the trial were statistically adjusted for differences in total HoNOS scores at baseline and for study site fixed effects (randomisation was stratified by trial site). The adjustments were performed by fitting a generalised linear model to the participant-level data. Intervention 'treatment effects' were identified by inclusion of a trial allocation dummy variable in each statistical model. An appropriate transformation was then applied to the model coefficients to obtain estimated differences in mean cost and mean outcomes between the trial groups. Given low intra-cluster correlation coefficients observed across primary and secondary outcomes in the clinical effectiveness analysis, statistical models were fitted without further adjustment for trial clustering at the team level. Differences in the probability of participants transitioning from cluster 10 into each of the overarching-clusters (low, moderate, or high cost) were adjusted for baseline HoNOS scores, trial site fixed effects and participant age. Probabilities were estimated using an ordered logit model fitted to participant-level data.

Sampling error and uncertainty

Following normal reporting standards, 95% CIs are presented for each adjusted difference estimate. To be consistent with the decision-analytic principles underpinning economic evaluation, uncertainty linked to trial sampling error is also characterised probabilistically (excluding the analysis of MHCs). Specifically, we report the probability that the true (unobserved) population difference in mean cost between intervention and control participants is positive based on trial sample information (i.e. higher in the intervention arm) and correspondingly the probability that the difference in mean days spent in favourable living arrangements, paid and unpaid employment and education and training is positive. When evaluating the cost-effectiveness of the intervention from a mental health system perspective, we present the probability of intervention dominance versus either sEIP or the existence of a trade-off between cost and clinical outcome.

Probabilities were derived by simulating a plausible distribution of unknown population values for (adjusted) differences using bootstrap re-sampling (with replacement) from the trial data. For each outcome, n = 1000 bootstrap sample replicates were generated. Statistical models were then fitted to each replicate to generate a distribution (cumulative density) of model coefficients describing the treatment effect of the intervention. The required probabilities equate to the proportion of each distribution consistent with the outcome of interest (e.g. a positive difference in mean cost). The mean (expected) value from a distribution is treated as the 'best' estimate of the effect of the intervention given uncertainty regarding its true value. For the cost-effectiveness analysis, a joint distribution of plausible combinations of mean cost and clinical outcome differences was produced by fitting cost and clinical outcome models jointly to each

bootstrap replicate. We present a scatterplot of this distribution and use this as a basis for making inferences regarding the cost-effectiveness of the intervention.

Imputation for missing data

There were two types of missing information within the case note data: unrecorded participant contacts with specific service items on the study proforma (including no record of zero contact where relevant) over one or both 6-month periods comprising the trial follow-up; and incomplete data for costing purposes where service contacts were indicated on forms (e.g. where dosage was missing for costing medication usage, length of hospital admission was not detailed). If data on contacts made was absent for both 6-month periods, the cost of service contacts over 12-month of follow-up were treated as missing. If service contacts were indicated on the pro-forma for one period but not the other, a zero value was imputed for the 6 months where the information on contacts was absent. We followed published guidance for handling missing data in economic evaluations of clinical trials when imputing for the remaining missing case note data and imputed only at the level of total mental health system cost. Multiple imputation (using mean predictive matching) was used to create $N = 5$ imputed data sets followed by the application of Rubin's rule when fitting models to the imputed data to evaluate adjusted differences in total mental health system costs. Missing total HoNOS scores at baseline were mean imputed ensuring that the imputed values are independent of treatment allocation. Missing total HoNOS score at 12 months were multiple imputed as specified above. This assumes that data are 'missing at random'. Subcategories of mental healthcare costs (planned and unplanned care costs) and MHC outcomes were modelled on a complete case basis.

For all analyses based on self-report data, we excluded participants who were not interviewed at the 12-month follow-up. For those participants who were administered the AD-SUS ($N = 232$), multiple imputation (mean predictive matching) was again used to impute for missing data with the imputations carried out for aggregated subcategories for wider system care contacts (NHS community/hospital, non-NHS and police contacts) and for each social outcome measure.

Sensitivity analysis

To evaluate whether the COVID-19 pandemic and the associated national policy response may have impacted on cost comparisons we undertook a sensitivity analysis. This compared our 'base-case' adjusted differences in mean cost values with those obtained from statistical models that further adjusted for whether each participant entered the EYE-2 study at a date pre or post 23 March 2020 (the date of commencement of the national lockdown in England). This was repeated for the statistical models used to estimate differences in planned and unplanned care contacts and total societal costs.

All economic analyses (including statistical modelling) were undertaken using Stata (version 17).[147]

Results

Descriptive statistics

Descriptive data for the cost of planned and unplanned mental healthcare contacts are shown in *Table 17*. Case note data were extracted for all 1027 participants. Incomplete (missing) data for costing purposes were generally low, though variable across different service items (medication usage was the least complete item in terms of informational requirements for costing).

Costs of psychiatric bed-day usage over the 12-month follow-up accounted for the largest contribution to the overall cost of mental healthcare contacts for the study sample (82%) followed by contact with EIP staff (14%). SDs around individual items of planned and unplanned mental healthcare costs are large relative to the reported mean values, suggestive of a wide sample variation in frequency of contacts and cost. As is typical with healthcare utilisation data, the distribution of mental healthcare costs was generally positively skewed, indicating that a smaller proportion of participants incurred relative high levels of cost of care contacts.

TABLE 17 Descriptive data: mental healthcare contacts (case note data)

	Percentage of eligible sample (*n* = 1027) with at least 1 recorded contact, %	Mean cost over 12-month follow-up (£)	SD (£)	Percentage contribution to total cost, %	*N* (% of eligible sample with incomplete data for costing)[a]
Planned care contacts					
Medication	83	158	532	1	628 (39)
Early Intervention	92	1673	1111	14	947 (8)
Unplanned care contacts					
Psychiatric bed days	39	9901	20,452	82	945 (8)
Crisis team contacts	40	133	342	1	932 (9)
A&E contact	19	93	316	< 1	880 (14)
Mental Health Act	22	120	423	< 1	840 (18)
Section 136 *suite*	3	86	410	< 1	820 (20)
Ambulance	13	82	296	< 1	862 (16)

a The '*N*' value refers to the number of participants who had available service contact data for costing (as shown in the table). This includes cases where a '0' service contact value was imputed for either one of the 6-month periods constituting the 12-month period of follow-up, as per earlier guidance. Incomplete data for costing purposes is defined as instances where no value for the number of service contacts was recorded in the proforma for service contacts for either 6-month period or where other information required for costing (e.g. details of medication dosage) were unavailable.

Table 18 presents descriptive data for wider service use cost obtained from self-report data. All eligible participants were identified for interview at 12 months, excluding 150 participants who were lost to follow-up and 62 participants (6%) who were not approached. Eight hundred and fifteen participants were followed up by study researchers, of whom *n* = 127 could not be contacted due to lack of accurate contact information, *n* = 688 were contacted and *n* = 232 were administered the AD-SUS. Reasons for failure to interview of those contacted included: non-response to at least three telephone, text and/or written contacts (36% of those contacted, *n* = 249); refusal to participate (26%, *n* = 178); and consented but not completed (4%, *n* = 29). The AD-SUS data for those who were successfully interviewed were generally complete with only a small percentage of interviews returning incomplete information against specific service items.

A sample of *n* = 232 represents completion by 22% of the total eligible sample of participants (27% of those not lost to follow-up). The proportion interviewed in each arm (67.2% in the intervention arm and 32.8% in the EIP arm) was similar to the proportion of patients in each arm of the trial (64.2 % and 35.8%, respectively). The subsample interviewed had a similar mean age to the total sample (25.4 vs. 25.1 years), with a similar mean total HoNOS score at baseline (5.6 vs. 5.4). A higher percentage of the interviewed sample were of a white ethnic background (59.7% vs. 51.8%) and a lower percentage identified as male (59.5% vs. 63.6%).

Over 70% of the sample reported at least one contact with their GP over the 12-month period, and 11% reported spending time in staffed accommodation, which contributed by far the highest percentage to the overall wider service use cost (64%). Contact with the police was a comparatively rare event: 6% reporting at least one contact on account of being the victim of crime and only 3% reporting that they had been arrested on at least one occasion.

Table 19 presents descriptive information regarding intervention costs across the whole sample. The most substantial resource component was the value (opportunity cost) of time allocated by care co-ordinators and EIP team leads at intervention services in attending training (estimated to be £265,609). See details of training in *Appendix 5*. The largest financial outlay contributing to the cost of the intervention was on website development at a cost of £25,000 (or £6369

TABLE 18 Descriptive data: wider system contacts (self-report data)

	% (*n* = 232) of those interviewed who reported at least one contact	Mean cost over 12-month follow-up (£)	SD (£)	% contribution to total cost	*N* (% of those interviewed with incomplete data for costing)[a]
NHS hospital contacts (non-psychiatric)					
Elective admission	< 1	19	288	1	227 (2)
Day case	2	28	236	1	227 (2)
Non-elective short stay	2	19	149	1	227 (2)
Non-elective long stay	6	213	1862	6	228 (2)
Outpatient	28	139	321	4	230 (1)
A&E contact with ambulance	3	40	273	1	229 (1)
A&E contact walk-in	14	39	127	1	227 (2)
NHS community-based service contacts					
GP	72	153	186	5	211 (9)
GP nurse	30	22	60	1	209 (10)
NHS Direct	19	4	9	< 1	212 (9)
NHS psychiatric helpline	8	2	9	< 1	212 (9)
NHS help line	11	6	25	< 1	212 (9)
NHS walk-in clinic	9	22	92	1	212 (9)
Non-NHS community-based service contacts					
Day centre local authority	2	3	26	< 1	212 (9)
Day centre private	2	1	8	< 1	212 (9)
Counsellor non-NHS	4	20	150	1	212 (9)
Psychiatrist non-NHS	2	10	79	< 1	212 (9)
Psychotherapist	5	67	563	2	212 (9)
Drop-in social centre	1	6	62	< 1	212 (9)
Social worker	9	35	157	1	212 (9)
Housing support worker	13	90	670	3	212 (9)
Employment advisor	19	88	323	3	209 (10)
Benefit advisor	20	55	183	2	211 (9)
Citizen advisor	6	25	175	1	212 (9)
Accommodation	11	2114	7759	64	232 (0)
Police contacts					
Police arrest	3	15	91	< 1	227 (2)
Contact with police for being a victim	6	116	1114	4	228 (2)

a The '*N*' value refers to the number of participants successfully interviewed using the AD-SUS questionnaire for whom there was complete data for costing purposes. Incomplete data refers to cases where service contact information was missing for costing a specific service item (e.g. missing information on frequency of contact over 12 months).

Note
% contribution to total cost > 100% due to rounding.

TABLE 19 Intervention costs

Activity/cost item	Cost (£)
Training: Facilitator and PPI time input across all EIP services in the intervention arm	24,668
Training: Time input from care co-ordinators and team leads who attended training in the delivery of the intervention across all EIP services in the intervention arm	265,609
Training: catering and room hire	4777
Development of intervention manual	1542
Intervention booklets	1.84
Cost of website site development (annual equivalent)	6369
Intervention cost	467 per participant receiving the intervention

as an annuitised equivalent). Overall cost of implementing the intervention was estimated at £467 per study participant attending a service randomised to the intervention arm of the trial.

Descriptive data for the three social outcomes at 12-month follow-up in the subgroup of participants administered the AD-SUS revealed that AD-SUS had high levels of completeness for calculating days of exposure to employment and education and training, though over 10% of interviews returned incomplete information for calculating the number of days spent in independent living arrangements. Based on participants with complete data: an average of 237 days were spent living in stable and independent living arrangements (65% of the of the 12-month period of follow-up); 52 days in paid or unpaid work (14% of the follow-up period); and 89 days undertaking education or training (24% of the follow-up period). Large SDs around these averages are indicative of a wide variability in responses to questions about these three outcomes provided by participants (see *Appendix 6*, *Table 41*).

Table 20 presents descriptive information across the whole sample regarding the transition to different MHCs. At 12-month follow-up, 92% of study participants across both arms of the trial had scores indicative of a transition to a cluster consistent with a de-escalation in clinical need and a trajectory towards discharge from EIP services as defined by Royal College of Psychiatrists guidance.[140] Of these (*N* = 616), 81% were within a low-cost cluster (11 or 12), the remainder (19%) in a moderate-cost cluster (13, 16 or 17). Of the overall sample (*N* = 673), 3% remained in in the FEP cluster (10) and 5% transitioned to a high-cost cluster (14 or 15) associated with a marked escalation in clinical need.

TABLE 20 Mental health cluster allocation at 12-month follow-up (*N* = 673[a])

	% in each cluster	*N*
Ongoing recurrent psychosis – low symptoms (cluster 11)	56	376
Ongoing recurrent psychosis – high disability (cluster 12)	18	123
FEP (cluster 10)	3	23
Ongoing recurrent psychosis – high symptom and high disability (cluster 13)	8	51
Dual diagnosis (cluster 16)	4	29
Psychosis and affective disorder – difficult to engage (cluster 17)	6	37
Psychotic crisis (cluster 14)	2	13
Severe psychotic depression (cluster 15)	3	21

a Cluster allocations based on participants with complete HoNOS data.

Cost of mental healthcare contacts: group comparisons and cost-effectiveness analysis

Adjusted differences in the mean cost of planned and unplanned care contacts per participant between the trial arms and differences in mean total mental health system cost across the whole sample are presented in *Table 21*. The expected population difference in the mean cost of planned care contacts was −£25 (i.e. mean costs is £25 lower in the intervention arm; 95% CI −£173 to £122) with a corresponding 40% probability that the cost would be higher in the intervention arm. The expected difference in the mean cost of unplanned care contacts was −£1280 (95% CI −£4126 to £1565) with a 19% probability that unplanned care costs would be higher in the intervention arm. The expected difference in mean total mental health system cost between the trial arms (inclusive of intervention cost) was estimated to be −£788 (95% CI −£3571 to £1994) with a probability of 28.8% that the total mental health system costs would be higher for intervention trial participants. The estimated difference in total HoNOS score at 12 months is −0.134 (95% CI −1.101 to 0.833) with a probability of 58% that patients in the intervention arm will have a better score (where a negative difference indicates an improvement).

Figure 11 presents the results from the cost-effectiveness analysis from a mental health system perspective across the whole sample, using total HoNOS scores as the measure of clinical outcome; the scatter plot shows the joint distribution of plausible combinations of differences in mean total mental health system cost and mean total HoNOS scores, the expected (best estimate) values and a 95% confidence ellipse (95% of the joint distribution lying withing the ellipse). For presentational purposes adjusted differences in mean HoNOS scores were 'inverted' so that a positive difference indicates a better mental health state for intervention participants (corresponding to values along the horizontal axis to the right of the origin). The figure also indicates the proportion of the distribution within each quadrant of the scatter plot corresponding to four possible cost-effectiveness outcomes. These proportions indicate the probability that the true unobserved combination of population mean cost and outcome differences would be consistent with either EYE-2 or EIP dominance or a trade-off between cost and clinical outcome.

Given sample information on cost and outcomes from the trial, the intervention would be expected to dominate sEIP in cost-effectiveness terms within the wider service population: the expected mental health system cost was lower (a difference of −£788 per participant) and mean clinical outcomes were marginally superior (improvement in total HoNOS score of 0.13) for intervention participants. Given sampling error in the data, there was a 43.4% probability that intervention dominance would be the correct conclusion to draw regarding the cost-effectiveness of the intervention; a 14.1% probability that sEIP would dominate; a 27.8% probability that mental health system costs would be lower for EYE-2 and clinical outcome superior sEIP; and a 14.7% probability that total mental health system cost would be higher and clinical outcome superior in EYE-2.

Wider system costs and social outcome: group comparisons

Table 22 presents the adjusted differences in wider system costs between the trial arms based on analysis of the subgroup that provided self-report data. The expected population difference in the mean cost of NHS (non-psychiatric) service contacts was −£156 (95% CI −£549 to £236) with an 18% probability that this difference would be higher in the intervention arm. The expected mean cost of non-NHS community-based service contacts were £320 higher for intervention participants (95% CI −£3058 to £3698) with a probability of 63% that the difference between arms would be positive. The expected population difference in the mean cost of police contacts was £790 (95% CI −£1471

TABLE 21 Cost of mental healthcare contacts: adjusted differences

	Adjusted difference in mean cost (expected value) (£)	95% CI	Probability of higher mean cost for intervention participants (%)	*N*
Planned contacts	−25	−£173 to £122	40	948[a]
Unplanned contacts	−1280	−£4126 to £1565	19	948[a]
Total mental health system cost	−788	−£3571 to £1994	28.8	1027[b]

a Available case analysis.
b Analysis based on imputed data sample (using multiple imputation methods).

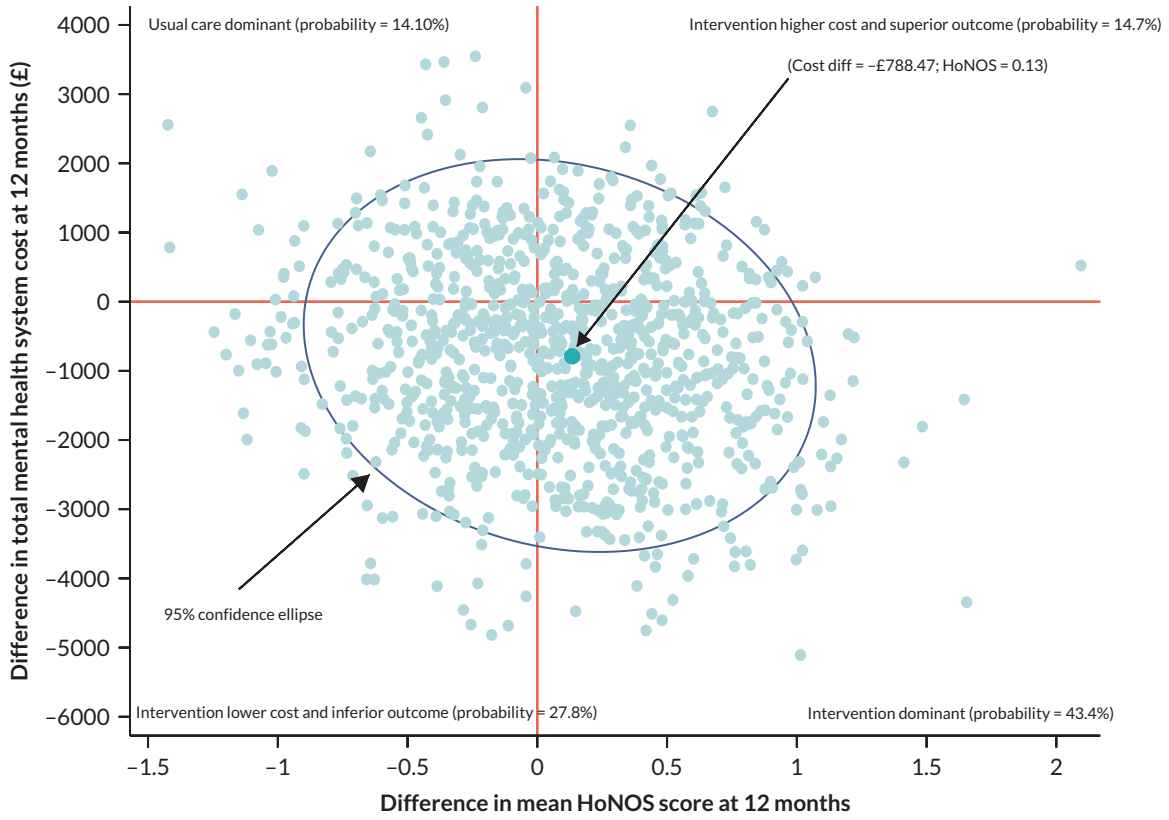

FIGURE 11 Cost-effectiveness analysis: joint distribution of total mental health system cost and clinical outcome differences. This analysis allows for the correlation between total mental health system cost and the total HoNOS score at 12 months.

to £3050) with an 82% probability that cost of police contact would be higher in the intervention arm. The expected population difference in overall mean cost of wider care system contacts between trial arms was £563 (95% CI −£1636 to £2761) with a 69% probability that wider system costs would be higher in EYE-2.

Total 'societal' costs sum together for each trial participant, the wider care system costs and total mental health system costs (including the cost of the intervention). To make this aggregation, analysis of societal costs *excludes* any participant who did not provide self-reported information about wider service contacts through the AD-SUS (irrespective of whether they had the requisite case note data for estimating costs of mental healthcare contacts) and so is based on

TABLE 22 Wider system and societal cost: adjusted differences

	Adjusted difference in mean cost (expected value) (£)	95% CI	Probability of higher mean cost for intervention participants (%)	N[a]
NHS service contacts (non-psychiatric hospital/community)	−156	−£549 to £236	18	232
All non-NHS community-based service contacts	320	−£3058 to £3698	63	232
Police contacts	790	−£1471 to £3050	82	232
Total wider system cost	563	−£1636 to £2761	69	232
Total societal cost	−526	−£7031 to £5980	43	232

a All models based on imputed data samples (using multiple imputation methods).

a subsample. The expected population difference in mean total societal cost between the trial arms (see *Table 22*) was −£526 per participant (−£7031 to £5980) with a probability of 43% that the difference would be higher in EYE-2.

In this subsample, the expected difference in mean days spent in stable and independent living was 5.73 days (95% CI −1.79 to 13.25), for time in paid or unpaid employment was 7.56 (95% CI −35.64 to 50.76) and for involvement in education and training was 30 days (95% 1.52 to 53.68). Probability of a positive outcome was: 98% for days in stable and independent living; 77% for days in paid and unpaid employment; and 99% for days undertaking education and training (*Table 23*).

Mental health clusters: group comparisons

Early Intervention in Psychosis services did not use item 13 of the HoNOS or the SARN, so several assumptions were made to impute missing values. As patients were new FEP service users, item A (historical agitated behaviour) was derived from the highest HoNOS score for this item at baseline or 6 months. Item B (historical self-harm) was derived similarly. Item D (engagement) was derived from the deidentified engagement data. Item 13, C and E were missing and rated 0: Item 13 is non-psychotic beliefs and item C relates to safeguarding of other children/vulnerable adults both of which may be present in psychosis clusters but are not expected, and the latter may be less common in this younger age group. Items scored 4 were recoded to 3 to run the algorithm, and red rules were applied according to the clustering guidance.[140,145,146]

Table 24 contains adjusted differences in the predicted probability of transitioning from the EIP MHC (cluster 10) at randomisation into a low-, moderate- or high-cost MHC at the 12-month follow-up. Intervention participants had a marginally lower probability of transitioning to either the moderate- or high-cost cluster: probability difference of −0.02 (95% CI −0.068 to 0.032) and −0.01 (95% CI −0.024 to 0.011), respectively. The predicted probability of transitioning to the low-cost clusters was marginally higher for intervention participants: probability difference of 0.02 (95% CI −0.043 to 0.09). There is substantial uncertainty in these data due to the assumptions required to produce the clusters.

Sensitivity analysis

Results from the sensitivity analysis (adjustments made for participants who entered the study pre- or post-national lockdown) made little difference to cost comparisons between arms (see *Appendix 6*, *Table 42*).

TABLE 23 Social outcomes: adjusted differences

	Adjusted difference in mean days (expected value)	95% CI	Probability mean days higher for intervention participants (%)	N[a]
Stable independent living arrangements	5.73	−1.79 to 13.25	98	232
Paid and unpaid employment	7.56	−35.64 to 50.76	77	232
Education and training	27.59	1.52 to 53.68	99	232

a All models based on imputed data samples (using multiple imputation methods).

TABLE 24 Adjusted difference in probability that the participant will transition to low, moderate or high cost (*N* = 673[a])

	Adjusted difference in probability	95% CIs
Low cost	0.02	(−0.043 to 0.09)
Moderate cost	−0.02	(−0.068 to 0.032)
High cost	−0.01	(−0.024 to 0.011)

a Models based on complete case HoNOS data.

Discussion

Summary of the health economic analysis

This within-trial economic evaluation provides evidence that the EYE-2 intervention lowered the mean cost of mental healthcare utilisation even after allowing for the additional costs incurred through implementation of the intervention. This conclusion is made with reference to the expected values, or 'best' estimates for a plausible range of possible values for differences in mean cost between trial arms, while also adjusting for any effect of baseline participant HoNOS scores and EIP site location on trial participant costs. There is, however, some margin for uncertainty around this finding with a 37% chance that total mental health system costs could in fact be higher for participants in the intervention arm given sampling error in the trial data. A cost-effectiveness analysis undertaken purely from a mental health system perspective (jointly examining total mental health system costs *and* total HoNOS scores and accounting for correlation between the two) suggested that that these overall cost reductions would be relatively unlikely to be achieved at the expense of inferior mean clinical outcome scores: a 72% probability that HoNOS scores would be superior for intervention participants but that this outcome advantage being only marginal in size based on the mean difference from a distribution of plausible values. There was a 43.4% probability that the dominance of EYE-2 observed based on mean values from a joint distribution of cost and outcome differences would hold.

The lower mean mental health system cost for intervention participants was largely explained by a lower mean cost of unplanned care. These average effects point to the intervention being effective in preventing the need for or shorter duration unplanned (emergency) mental healthcare response, at least within subgroups of the trial sample.

In an extension to the main analysis, we also examined (adjusted) cost differences for more granular items of mental health service categories to give an indication where the unplanned care cost reductions were likely to be concentrated (this did not form part of the main analysis described in the methods and results section and we present the adjusted differences in *Appendix 6*, *Table 44*). These point to lower mean unplanned care costs being driven largely by lower costs arising from psychiatric inpatient bed utilisation and, to a lesser extent, by reduced Mental Health Act assessment costs and costs of crisis resolution team contacts. All these cost reductions were partially offset by higher costs of Section 136 suite utilisation and of crisis ambulance usage for intervention participants.

Our main findings regarding mental health system cost and cost-effectiveness carry a degree of uncertainty: while lower unplanned care costs were expected to be the most likely outcome for the population (and are consistent with our 'best' estimate), there was still some margin for error: a 19% probability that population mean unplanned care costs would be higher for EYE-2 participants and a 28.8% probability that total mental health system costs (planned, unplanned and intervention costs) would be higher. In the cost-effectiveness analysis (see *Figure 11*), the most likely cost-effectiveness outcome was intervention dominance (a 43.4% probability) with only a small chance (14.1% probability) that, at the population level, sEIP would offer a lower cost alternative to the intervention with superior average clinical outcome scores. However, there was still a 27.8% probability that population cost and outcome differences could be suggestive of the intervention involving a trade-off of lower mental health system costs and inferior clinical outcome.

Analysis of wider system impacts based on participant self-report data suggested that, when taking a broader perspective, reductions in mental system costs would not be expected to be completely offset when including the effect of the intervention on wider service use: overall mean societal costs (inclusive of mental health system costs and wider care system costs) were still expected to be lower for intervention participants, despite higher costs attributable to police contacts and non-NHS community service contacts, though the margin for error attached to this assessment is considerable (a 43% probability that mean societal costs could be higher).

Social outcomes were, on average, superior for EYE-2 compared to sEIP participants (and estimated with comparative certainty given sampling error), with differences most marked regarding time spent in education and training [a difference of 30 more days (6 weeks) in education and training over the 12-month follow-up period]. Despite these positive findings, all results based on self-report data carry a significant caveat: only 22% of those eligible for inclusion in the analysis were interviewed. While the sample who were successfully administered the questionnaire were not wholly dissimilar to the wider eligible group based on sociodemographic characteristics and baseline HoNOS scores and attrition was similar for both trial groups, there is no guarantee of representativeness with regard to costs or the social

outcomes that were measured. We would therefore attach substantially less weight to the self-report-based findings compared to those based on case note data alone.

Analysis of participant transition to different MHCs at follow-up was intended to provide further insight into whether the intervention could impact on commissioning-related costs for mental health care, as indicated by national NHS tariffs applied to different MHCs. After adjustment, differences in the probability of transitioning into low-, moderate- or high-cost clusters were small with no real implication of cost of care from commissioning perspective over the period studied.

Interpretation of findings

Components of the intervention focused on reducing risk

The suggested lower mean mental health system costs as a result of lower unplanned admission, crisis team and Mental Health Act assessment costs in the EYE-2 intervention arm is consistent with a key focus of the intervention approach, training, resources and care co-ordinator feedback. A core component of the intervention is 'collaboration and choice . . . regarding difficult treatment issues, risk and hospital admission, which ordinarily impact on engagement' (p. 7).[47] The training manual involves a specific section on using the EYE-2 engagement approach in the context of risk (*Project document 2*: EYE-2 consultation and training manual; pp. 17–21), two of the six core group activities that comprise the training programme focus on how to maximise engagement, open and honest communication in the context of risk and potential hospital admissions. The expectation was that a more engaging, open and transparent approach would enable EIP clinicians to stay focused on patient's goals, encourage patients to be more open about risks, have more tools for managing crises, and so potentially reduce the demand for unplanned crisis support. This section proved especially popular with some staff, and on occasion the example case studies were expanded upon, by staff wishing to bring their own anonymised example cases for discussion and advice.

Alongside this focus for staff on maintaining collaboration in the context of risk, sections of the resources for patients, family members and friends also focused on these issues. Service users and young people in the original EYE project shared their concerns that a key barrier to engagement with mental health services was a fear of hospitalisation. Further, young people described challenges in opening up about their experiences, and family members noted the challenges in supporting their young person, when differences of opinion emerged around medication, crisis management and hospital admission. For these reasons, the Mental Health and Getting Help booklet, the EIP booklet and the Family and Friends booklet, contain sections on how to open up about experiences, and on the fact that Early Intervention services will work to keep people out of hospital wherever possible. These booklets also advise family members that working collaboratively with both the EIP service and the young person in crisis situations will provide the best support for their young person. The focus here was on encouraging service users and family members to talk about risk, so that Early Intervention in Psychosis teams could then work to reduce risk, relapse and admissions. As one care co-ordinator put it, in the implementation study:

> *It might be a prompt for someone to talk to us about something that they may not have been talking about before, particularly kind of around suicidal thoughts maybe because that might be something that's more difficult for someone to share, or even just voice hearing sometimes . . . they just don't want to tell you or don't know the language to tell you. And then here we go, it's all kind of written down for me. So, for a client to be able to, to be given a language to share that, I think reduces risk.*

Components of the intervention focused on a young person's goals

The finding of enhanced social outcomes, and specifically enhanced time spent in education employment and training, carries the significant caveat that it was limited to a subsample who completed the 12-month interview. The findings are, however, consistent with a second key component of the EYE-2 intervention which is to enable mental health staff to provide hopeful support for a young person with their meaningful goals and needs (see p. 748 and *Chapter 3*). A key aim of the EYE-2 intervention was promoting engagement and mental health by active listening, supporting young people with their *own* goals, being honest, and providing choice. This formed a further key component of the manual' (pp. 11–16) and training group activity. In addition, the treatment choices booklet (see *Project document 11*) includes a

whole section on support for work, education and things that you do, and this was provided to young people and their families as part of the EYE-2 intervention.

Limitations

The analysis of planned and unplanned mental healthcare contacts was restricted to a sample powered to detect differences in the study primary outcome (time to service disengagement). A larger trial sample, while more costly to deliver in research terms, would have yielded a more confident assessment of true population differences in cost and other outcomes in the presence of sampling error. Computational limitations also limited the number of bootstrap sample replications that could be generated to arrive at 'best estimates' of cost and outcomes differences uncertainty around these estimates: our estimates of the margins of error around central estimates are therefore in themselves subject to a degree of uncertainty. The analysis of wider care system costs and social outcomes must be viewed with particular caution as only 22% of the eligible study sample provided details about their wider service use, living arrangements, employment and education/training outcomes. While attrition was similar for both trial arms and the subsample interviewed were not dissimilar to the wider study sample, there remains considerable uncertainty as to whether those who were not interviewed were comparable in terms of the study outcomes of interest. Our analysis of MHCs relied on incomplete data on HoNOS items necessary for implementing a pre-existing deterministic algorithm designed to allocate service users to specific MHCs based on their HoNOS scores. Despite this limitation, it would seem unlikely that the availability of the missing data would have changed our core conclusions from this analysis. Finally, our analysis did not consider the effect of the intervention on quality-adjusted life-years lived for participants, and therefore it was not possible to gauge (on a within-trial basis) whether the intervention could have been regarded as 'cost-effective' when judged against current decision thresholds used to guide resource allocation in the NHS.

The health economic conclusions, while providing being consistent with key aims, and components of manuals, training programme and resources were still subject to a degree of uncertainty: comparisons were not specifically powered to detect effects relating to cost differences and had some margin for error when considering CIs in standard tests in the EYE-2 arm compared to the sEIP arm. Furthermore, a key limitation of the wider health economic evaluation is that only 22% of the total sample (27% of those not lost to follow-up at 12 months) completed the wider service use survey at 12 months. This is not entirely surprising as this survey was the only part of the study that required that service users be contacted for informed consent, and all attempts to contact people commenced in lockdown after the start of the COVID-19 pandemic. Nevertheless, this subsample was similar to the overall sample in most demographic and clinical characteristics with the exception of comprising slightly higher proportions of participants who were white and female, across both arms of the subsample.

Conclusions

These results provide an indication that the EYE-2 intervention may be associated with lowered mean cost of mental healthcare utilisation as a result of lower unplanned nights in hospital, crisis and Mental Health Act contacts across the whole sample. A cost-effectiveness analysis carried out from a mental healthcare provider perspective suggested that the EYE-2 intervention was more likely to be dominant in overall cost reductions in the context of marginally better mental health states, compared to sEIP. There was also an indication that the EYE-2 intervention was associated with more days in education and training, employment, and stable accommodation, but confidence in these findings is substantially limited by uncertainty over the representativeness of the subsample who were studied.

Chapter 7 Objective 4: the Early Youth Engagement-2 implementation process evaluation

Introduction

The large-scale mixed-methods process evaluation was founded on (1) NPT[74] and (2) logic models.[73] Quantitative data were collected using well-validated structured survey instruments that tested key features of the use of the EYE-2 intervention, including implementation/normalisation and therapeutic alliance. Qualitative investigations with purposively sampled clinicians and managers from each service explored the lived experience of using the EYE-2 intervention in practice and developed a rigorous analysis of factors that promoted and inhibited its implementation.

Typically, process evaluations focus on the dynamics of operationalising a complex healthcare intervention in its organisational or service delivery context.[147,148] Recent methodological and theoretical writing about process evaluations and implementation contexts have emphasised the complex, emergent processes that occur when an intervention is operationalised within a specific setting.[149–152] They tend to see the wider implementation context as more or less stable. However, in the EYE-2 trial, as in many studies conducted during COVID-19, this cannot be assumed as the context was massively disrupted by the effects of the pandemic. These included the most severe restrictions on freedom of movement and association ever placed on the population of the UK; the disruption of health and social care services; and disruption of public transport,[153] which had a profound impact on professional practice, service user behaviour and service delivery. This shaped the delivery of the EYE-2 intervention and affected relations between clinicians and service users, their families and friends. It is impossible to overestimate the effects of the pandemic on the conduct of the trial, and the ways that it shaped the implementation and use of the intervention.

Aims and objectives

To develop and test a framework for implementation through a large-scale process evaluation using (1) NPT[74] and (2) logic models,[73] incorporating all clinicians involved in EYE-2 intervention delivery, assessed through questionnaires and qualitative interviews at the start, middle and end of the trial.

Outline of the normalisation process theory

Implementation Science approaches to process evaluation typically focus on the methods through which evidence-based practices become incorporated into the delivery of health and social care.[154] Implementation research using NPT takes a slightly different tack because it is founded on understanding implementation processes as complex, emergent patterns of purposive social action. Through a series of iterations, NPT has developed a set of theoretical constructs that identify, characterise and explain core mechanisms that motivate and shape implementation processes.[152,155–157] The core mechanisms of NPT have been validated in multiple studies and systematic reviews.[158–160] NPT begins with two key propositions.

- *Implementation processes are characterised by the translation of the strategic intentions of one group of actors into the everyday practices of others*.[16] In health care, these processes usually come about as deliberately initiated attempts to introduce new, or modify existing, ways of delivering and organising care in practice. Implementation processes of this kind are normally institutionally sanctioned; formally defined; consciously planned; and intended to lead to defined outcomes.[161]
- *The core of implementation is purposive social action characterised by collective action and collaborative work*.[162] This is 'the work that actors do as they engage with some ensemble of activities (that may include new or changed ways of thinking, acting, and organising) and (. . .) becomes routinely embedded in the matrices of already existing, socially patterned, knowledge and practice'.

These key propositions define the 'engine room' of implementation processes, while a set of defined mechanistic constructs permit detailed analysis and explanation of implementation processes. These have recently been consolidated into a single theoretical model and made available as a coding manual for qualitative analysis and instrument development.[163] This is described in *Table 25*, in terms of implementation contexts, mechanisms and outcomes which form the scaffolding for the process evaluation in this chapter.

Key components and contextual influences derived from logic models

Strategic intentions and components of the Early Youth Engagement-2 model

Key intentions and components of the EYE-2 intervention are a *belief* in promoting engagement and mental health, through (1) enhancing *relationships* through active listening, supporting young people with their own goals and (2) *processes* of being honest, open and collaborative, and providing choices in the context of risk. Components of the intervention comprise (1) motivational and goal-focused *processes* to promote engagement, (2) social network *processes* aimed at harnessing *relational* support for enacting treatment goals and choices and (3) psychoeducation *procedures*, delivered largely through care co-ordinator *roles*, and utilising the EYE-2 *resources (objects)* including the website and booklets in systematic ways to achieve desired outcomes. The extent to which these processes are implemented is expected to affect outcomes.

Key system-based contextual influences

Key contextual influences derived from the system-based logic model and expected to influence processes and outcomes included (1) implementation capacity: organisational support, caseload size and funding model and space, (2) implementation context: geographical, socioeconomic, sociocultural (e.g. staff turnover, discharge management policies and intake criteria), epidemiological and service user characteristics (e.g. ethnicity, first language, literacy, motivation, risk) and (3) implementation processes and execution.

Strategic intentions, implementation capacity, context, and execution, are considered and where appropriate, evaluated for their impact on effectiveness of the intervention (see *Chapter 5*).

Method

A prospective mixed-methods process evaluation was developed to investigate the delivery of the intervention, longitudinally over 34 months, informed by NPT and trial-specific logic models (see *Figures 2* and *3*).

Participants

Participants were all clinicians delivering EYE-2 and/or EIP services as part of the randomised trial. All participants provided written informed consent.

Procedure

The evaluation comprised four components over four time points.

Training evaluation

All clinicians who attended the data collection or the intervention training were invited to provide feedback regarding the training, in questionnaires provided pre and post training.

Initial Early Intervention in Psychosis delivery evaluation

At round one, one participant from each sEIP and EYE-2 team completed a semi-structured interview regarding EIP service delivery context that may impact on EYE-2 implementation and outcomes.

Longitudinal quantitative evaluation

All clinicians involved in the delivery of the intervention or the sEIP service were invited to complete a questionnaire concerning EYE-2 or sEIP service delivery early, mid and late intervention. The questionnaires aimed to evaluate adherence to EYE-2 and EIP models, policies and practices.

TABLE 25 Normalisation process theory: implementation domains and theory constructs

Implementation domains	*NPT constructs*			
Implementation contexts. Patterns of social relations and structures that unfold over time and across settings. They make up the implementation environment.	*Strategic intentions.* How do contexts shape the formulation and planning of interventions and their components?	*Adaptive execution.* How do contexts affect the ways in which users can find and enact workarounds that make an intervention and its components a workable proposition in practice?	*Negotiating capacity.* How do contexts affect the extent that an intervention and its components can fit, or be integrated, into existing ways of working by their users?	*Reframing organisational logics.* How do existing social structural and social cognitive resources shape the implementation environment?
Implementation mechanisms: Mechanisms are revealed through purposive social action – collaborative work – that involves the investment of personal and group resources to achieve goals.	*Coherence building.* How do people work together in everyday settings to understand and plan the activities that need to be accomplished to put an intervention and its components into practice?	*Cognitive participation.* How do people work together to create networks of participation and communities of practice around interventions and their components?	*Collective action*. How do people work together to enact interventions and their components?	*Reflexive monitoring.* How do people work together to appraise interventions and their components?
Implementation outcomes: The practical effects of implementation mechanisms at work.	*Intervention performance.* What practices have changed as the result of interventions and their components being operationalised, enacted, reproduced, over time and across settings?	*Normative restructuring.* How have working with interventions and their components changed the norms, rules and resources that govern action?	*Relational restructuring.* How have working with interventions and their components changed the ways people are organised and relate to each other?	*Sustainment (normalisation).* How have interventions and their components become incorporated in practice?

Longitudinal qualitative evaluation

A subsample of clinicians in EYE-2 teams completed a qualitative interview to explore barriers and facilitators to intervention delivery in relation to context and turbulence. The logic models were introduced to facilitate discussion. The aim was to include 2 clinicians and 1 manager at each intervention team, with at least 10 participants at the same 3 time points.

Questionnaires were completed online on Qualtrics. Interviews were conducted by telephone or video-consultation by an EIP RA from another site, to promote openness in relation to service delivery and were audio-taped and transcribed for analysis.

Measures

A detailed summary of the content of training and implementation questionnaires and qualitative interview topic guides is provided in *Appendix 7*.

The training questionnaire

The training was evaluated quantitatively in terms of attendance, experience of the training, changes in confidence in using a range of EYE-2 engagement approaches, attitudes towards implementation and qualitative feedback on helpful and unhelpful aspects. A complete description of the EYE-2 training analysis is provided in *Appendix 5*.

The Early Youth Engagement-2/Early Intervention in Psychosis implementation questionnaire

These questionnaires explored

- *Contextual factors:* COVID-19 and other factors (team views, service user insight, reading ability, service user feedback, own ability and own confidence).
- *Implementation processes:* NOMAD tool[164] of attitudes and behaviours towards implementation coherence, cognitive participation, collective action, reflexive monitoring and normalisation, and measures of pride, professionalism, and confidence.
- *Intervention outcomes*: use of EYE-2 approaches and resources; and the clinician-rated Working Alliance Inventory.[165]

Clinicians were also asked to record any standard EIP social/activity groups offered, training received and demographic details and in the EIP arm only, inadvertent use of the EYE-2 resources (contamination).

The EYE-2 questionnaire was used to describe a threshold for effective implementation based on clinicians' use of EYE-2 resources. A composite mean fidelity score was calculated for each clinician, by averaging their individual scores for use of each of the intervention resources and providing a mean composite score ranging from 0 to 4. Summary statistics for fidelity to the intervention are reported for the intervention group and for each cluster (team), by averaging the scores for all clinicians in each team who completed the questionnaire at each of the three time points (see *Table 14*). These data are presented in *Chapter 5*.

The Early Intervention in Psychosis and Early Youth Engagement-2 qualitative interviews

The EIP qualitative interview was conducted with reference to standard EIP processes and policies and in light of emerging patterns observed as part of the EYE-2 programme, including numbers assessed and accepted onto caseloads, the impact of AWTS and assessment processes, the nature of clients taken on, changes in EIP service delivery, and future needs.

The EYE-2 qualitative topic guide was developed and informed by NPT and the logic models outlined in *Chapter 3*. It asked about training, understanding and implementation of the EYE-2 intervention and impacts of COVID and other contextual factors.

Primary and secondary outcomes

Primary intervention outcomes were pre-defined as:

1. use of approaches and resources and fidelity to the EIP and EYE-2 model;

2. the working alliance inventory which explored changes in therapeutic relationships;
3. the implementation process scores on the NOMAD tool[164] in the EYE-2 arm.

The secondary outcomes were the themes derived from the qualitative analyses.

Elements of the Royal College of Psychiatrists EIP self-assessment tool,[54] national and local service-level data were collected in both groups to describe service delivery and context and incorporated into the main effectiveness analysis.

Hypotheses

The process evaluation did not test specific hypotheses regarding the implementation process.

It was hypothesised that the intervention effectiveness would be moderated by implementation fidelity as measured by the process evaluation questionnaires. Sensitivity analyses were planned to investigate whether the intervention effect was moderated by fidelity or context, and these are reported in the effectiveness analysis (see *Chapter 5*).

Analysis plan

The process evaluation followed a mixed-methods analysis approach. For training data, outcomes collected both pre- and post-training data were analysed using mixed-effects models, with time as the independent variable, and person and training group as random effects.

For quantitative questionnaire data, mean, SD and ranges were reported descriptively or presented graphically, and relationships between measures were explored using correlational analyses. Inferential statistical analyses were not presented due to small sample sizes, and multilevel clustering of participants, teams and arms across time points.

Qualitative data were analysed systematically using thematic analysis and a constant comparative analysis approach,[166] in NVivo (QSR International, Warrington, UK) version 12.5.0. and for EYE-2 data, themes were mapped onto the NPT framework, across context, processes and outcomes.

The NPT framework enabled consideration of specific changes that would be required to deliver the EYE-2 approach at an individual, and service level, to enable real, meaningful change in how individuals work, and services are delivered, based on core EYE-2 principles.

Results

Trial timings

Critical timings for training, intervention delivery, COVID-19 pandemic and process evaluation are presented in *Table 26*. Round 1 of the process evaluation ran immediately before the onset of the COVID-19 pandemic. Rounds 2 and 3 ran through the pandemic.

Participant demographic and descriptive data

Demographic data for participants in all sections of the process evaluation are presented in *Tables 27–29* (see *Appendix 5*, *Tables 39* and *40 for training data*). Staff who consented to attend training and provided feedback are described in detail in *Chapter 5*.

Findings from the process evaluation

Data arising from each analysis component are incorporated as appropriate to illustrate our understanding of the context, processes and outcomes of implementation of EYE-2.

Implementation context

Two major contextual changes occurred in tandem with the EYE-2 intervention, which impacted on and shaped intervention delivery in both arms of the trial. The first of these was the COVID-19 pandemic. The first-ever national lockdown commenced 10 months into intervention delivery; the pandemic continued throughout the remaining

TABLE 26 Critical timelines for the process evaluation

	Jan 19	May 19	Aug 19	Nov 19	Feb 20	May 20	Aug 20	Nov 20	Feb 21	May 21	Aug 21	Oct 21
Training												
Intervention delivery												
COVID-19 pandemic												
Booster training												
Process evaluation Rounds 1–3												

TABLE 27 Demographics for participants who completed the quantitative implementation questionnaire

	Round 1 (*n* = 70)	Round 2 (*n* = 81)[a]	Round 3 (*n* = 68)[b]
Age Mean (SD) range	41.2 (11.1) 23–62	43.0 (11.0) 25–68	44.9 (11.8) 24–65
Gender *N* (%) male/ female/non-binary	12/53/0[c] (18.5/81.5)	20/48/1[d] (24.7/59.2/1.2)	17/51/0 (25/75/0)
Ethnicity *N* (%)	White 56 (87.5)[e]	White 57 (70.4)[d]	White 59 (73.5)
	Mixed 3 (4.7)	Mixed 3 (3.7)	Mixed 1 (1.5)
	Asian 1 (1.6)	Asian 1 (1.2)	Asian 2 (2.9)
	Black 4 (6.3)	Chinese 1 (1.2)	Chinese 1 (1.5)
		Black 7 (8.6)	Black 14 (20.6)
Religion	None 39 (60.9)[e]	None 47 (58.0)[f]	None 38 (55.9)
	Christian 22 (34.4)	Christian 19 (23.5)	Christian 27 (39.7)
	Muslim 2 (3.1)	Muslim 1 (1.2)	Muslim 1 (1.5)
	Catholic 1 (1.4)	Humanist 1 (1.2)	Jehovah's witness 1 (1.5)
			Prefer not to say 1 (1.5)
Care co-ordination	Yes 64 (97%)[g]	Yes 68 (84%)[f]	Yes 65 (95.5)
	No 2 (3%)	No 2 (2.5%)	No 3 (4.4)
Discipline	Team lead 4 (6.2)[c]	Team lead 4 (4.9)[h]	Team lead 2 (1.5)
	Nurse 28 (43.1)	Nurse 37 (45.7)	Nurse 39 (57.4)
	OT 14 (21.5)	OT 7 (8.6)	OT 8 (11.8)
	Social worker 17 (26.2)	Social worker 21 (25.9)	Social Worker 16 (23.5)
	Care co-ordinator 1 (1.4)	Psychiatrist 1 (1.2)	Psychiatrist 1 (1.5)
	Psychotherapist 1 (1.4)		Care co-ordinator 1 (1.5)
			Psychological therapist 1 (1.5)
Time in EIP	1 month to 16 years 9 months	3 months to > 10 years	1 month to 9 years 2 months

a 27 people completed R1.
b 45 people completed R1 (5) R2 (27) or both (13).
c Missing data for 5 people
d Missing data for 12 people.
e Missing data for 6 people.
f Missing data for 13 people.
g Missing data for 4 people.
h Missing data for 11 people.

TABLE 28 Demographics for participants who completed the EIP qualitative study (*N* = 20)

Team	Age	Gender	Ethnicity	Role/profession
L001	27	M	White British	Care co-ordinator/mental health nurse
L002	30	M	White British	Care co-ordinator/social worker
L003	57	F	White British	Care co-ordinator/social worker
L004	28	F	White British	Care co-ordinator/social worker

TABLE 28 Demographics for participants who completed the EIP qualitative study (*N* = 20) (*continued*)

Team	Age	Gender	Ethnicity	Role/profession
TV005	48	F	White British	Team manager
TV006	42	F	White British	Clinical lead/mental health nurse
TV007	43	F	White British	Psychologist
TV008	42	F	White British	Team leader
H009	43	M	White British	Care co-ordinator
H010	40	F	White British	Social worker
H011	50	M	White British	Care co-ordinator/mental health nurse
H012	50	M	White British	Team leader/mental health nurse
EA013	44	F	White British	Clinical nurse specialist/mental health nurse
EA014	36	F	White and Black Caribbean	Occupational therapist
EA015	59	F	White British	Care co-ordinator/mental health nurse
EA016	54	F	White British	Care co-ordinator/social worker
M017	31	M	White British	Care co-ordinator/social worker
M018	52	F	White British	Care co-ordinator/occupational therapist
M019	45	F	White British	Care co-ordinator
M020	50	M	White British	Care co-ordinator/mental health nurse

TABLE 29 Demographics for participants who completed the longitudinal EYE-2 qualitative interviews

	Age	Gender	Ethnicity	Role/profession
Round 1 (n = 11)				
L1	57	F	White British	CC – Social worker
L2	27	M	White British	CC – Mental health nurse
L3	30	M	White British	CC – Social worker
H4	40	F	White British	CC – Social worker
H5	43	M	White British	CC
M6	31	M	White British	CC – Social worker
M7	52	F	White British	CC – OT
TV8	42	F	White British	Clinical lead – Nurse
TV9	48	F	White British	Team lead – Nurse
EA10	59	F	White British	CC – Psychiatric nurse
EA11	54	F	White British	CC – Social worker
Round 2 (n = 10)				
TV21	56	F	White British	Mental health nurse
M22	36	F	White British	Mental health nurse
L23	39	F	White and Black African	Social worker

continued

TABLE 29 Demographics for participants who completed the longitudinal EYE-2 qualitative interviews (*continued*)

	Age	Gender	Ethnicity	Role/profession
L24	37	M	Black British	Mental health nurse
EA25	26	F	White British	Mental health nurse
H26	38	F	Chinese	Mental health nurse
EA27	61	M	White British	Mental health nurse/case manager
M28	41	F	White/mixed British	Mental health nurse
TV29	31	F	White New Zealander	Advanced mental health practitioner/team lead
H210	33	F	White British	Mental health nurse
Round 3 (n = 11)				
H31	49	F	White British	Acting team leader/OT
M32	35	F	White British	Team manager
M33	36	F	White British	Community mental health nurse
L34	34	M	White British	Team leader
EA35	49	F	White British	Team leader/community mental health nurse
H36	35	F	White British	Team manager
TV37	37	F	White British	Deputy manager/therapist
EA38	39	F	White British	Mental healthcare co-ordinator
TV39	29	F	White British	Care co-ordinator
L310	48	M	White British	Family intervention therapist
L311	31	F	White British/Italian	Senior clinical psychologist

16 months of the trial. From early in the trial there were threats of team closures and staff redeployment, use of PPE, reduced F2F work, increased video-consultations, remote and home working, increased staff sickness and turnover. This was a whole population cluster-RCT, and all clusters had commenced, so there was no pause in the trial during the pandemic.

The second impact was the NHS-England AWTS.[33] The AWTS incorporated a target that at least 60% of patients presenting with a first episode of psychosis be allocated to a care co-ordinator within a NICE-guidelines-compliant EIP service within 2 weeks of presentation to mental health services. EIP services were expanded to include patients aged 36–65 (over age 35) and patients presenting with an at-risk mental state (ARMS), and requirements to collect routine outcome data were instigated. NHS England provided investment and support to aid delivery, including new staff, and training in psychological and family interventions. Services were evaluated annually against targets through the annual National Clinical Audit for Psychosis-EIP.[127] However, this investment was staggered, varied by service and was not fully implemented by the end of the trial.

Strategic intentions

The *strategic intentions* are for use of the intervention and its components, as articulated in the process-oriented logic model (see *Chapter 3*). EYE-2 was developed in collaboration with clinicians and service users, to be both important and feasible for use in day-to-day work. The strategic intention was to provide a minimally disruptive, complementary, supportive framework of important tools (booklets, website, social groups) and approaches (motivational, systemic therapeutic alliance, psychoeducation), to enable staff to better engage young people. The intention was a *belief* in promoting engagement and mental health, through the enactment of the intervention.

Adaptive execution

The adaptive execution is the extent to which the context allows an intervention and its components to work in practice. *The adaptive execution* of EYE-2 meant that initially people understood the focus on individual goals and family support and that resources promoted engagement if 'used' not just 'given' and considered how to make time. It was recognised that booster trainings were needed, especially for new staff. Effort was required on the part of care co-ordinators and the EYE-2 teams.

The qualitative EIP data revealed that early in the trial at least four teams felt they had the resource and capacity to be flexible and take individuals onto caseloads when there was diagnostic uncertainty (see *Appendix 8*). This was consistent with previous EIP values and placed these services in a good position to deliver the EYE-2 intervention.

> M018: *'Really we are quite open in terms of assessment and interventions for people and our team is more likely to take people on where there's some diagnostic uncertainty you know because we are not sure where this is going. As a team we're really keen to put that person central to everything'.*
> L001: *'Generally we're quite flexible and we'll take them for like a more extended period of assessment'.*

However, COVID-19 had a negative impact on engagement across EIP and EYE-2 teams; the most negative impact was the reduced F2F contact throughout the pandemic (*Figure 12*).

In the EYE-2 arm, there was a marked monthly increase in EYE-2 website activity from March to June 2020, during the first national lockdown, with a smaller peak in November 2020 during the second lockdown, which may have ameliorated some of the impacts (*Figure 13*).

> L24: *'So, the website is something that I tend to promote a lot. Especially when things are virtual at the moment'.*
> H210: *'I think you've got the use of the website. So, if you were able to engage someone in a Zoom meeting then you could share your screen. You could utilize it'.*

However, the restrictions on contact undoubtedly hollowed out the EYE-2 intervention, de-prioritising the therapeutic value of working with social networks and social groups.

> M22: *'I suppose we can't ignore COVID. Like we've not been able to meet up. Social interaction has been curtailed by the pandemic hasn't it. So, it isn't something we would be recommending. Outside of COVID times it may have had a different effect, but certainly as it is now, we wouldn't have been promoting extra social communication'.*
> H31: *'The groups have been a bit more difficult . . . because we are such a dispersed and large locality it's very hard to run any groups and draw in service users. COVID obviously hasn't helped. The EYE-2 research assistants have tried their hardest to encourage service users to participate and move to online groups when COVID was its worst. But that's definitely been more difficult, so attendance has been quite poor'.*

Negotiated capacity

The negotiated capacity is the extent to which contexts allow an intervention and its components to be integrated into practice. Staff in the intervention arm identified that COVID-19 had a slight negative impact on use of EYE-2 resources, with impacts increasing as the trial progressed. The most negative impact was on the delivery of social groups which stopped completely for several months before gradually restarting by telephone or online (*Figure 14*).

Alongside COVID-19, service pressure, lack of resources and an increased stringency in the assessment process over time also impacted on capacity to deliver the intervention as planned. At least 10 out of 20 teams felt that acceptance had become more stringent with fewer borderline cases taken on due to service pressure and resource issues. Three teams spoke of links between the expansion to include over 35-year-olds and fewer young people being taken on, 14 teams referred to the complexity in those aged over 35, and 6 teams spoke of the impact on workload. The picture was of services that were at or beyond capacity, struggling to meet demands, leading to restrictions in EIP populations so that only the more severe, schizophrenia-spectrum patients were accepted (see *Appendix 8* for themes and quotes derived from the EIP qualitative study).

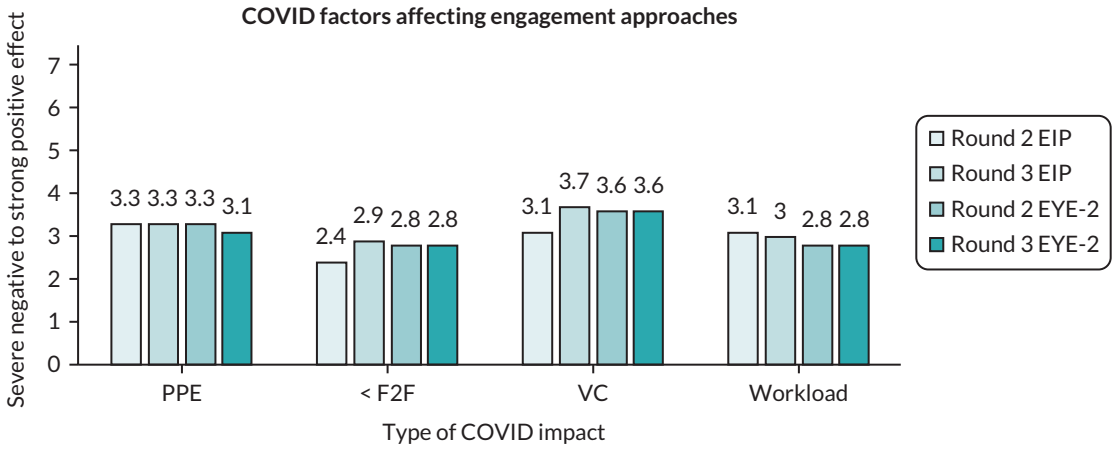

FIGURE 12 Coronavirus-19 factors affecting engagement in the EIP and EYE-2 arms from mid (R2 *n* = 81) to end of the intervention (R3 *n* = 68). Scored on a seven-point Likert scale. PPE = use of personal protective equipment, < F2F = reduced face-to-face contact, video consult = video consultation, workload = increased workload due to COVID-19 (SDs EIP R2: 1.2; 1.2; 1.3; 1.3; R3: 1.2; 1.0; 1.3; 1.3; EYE-2 R2: 1.3; 1.1; 1.3; 1.3; R3: 1.1; 1.3; 1.5; 1.5).

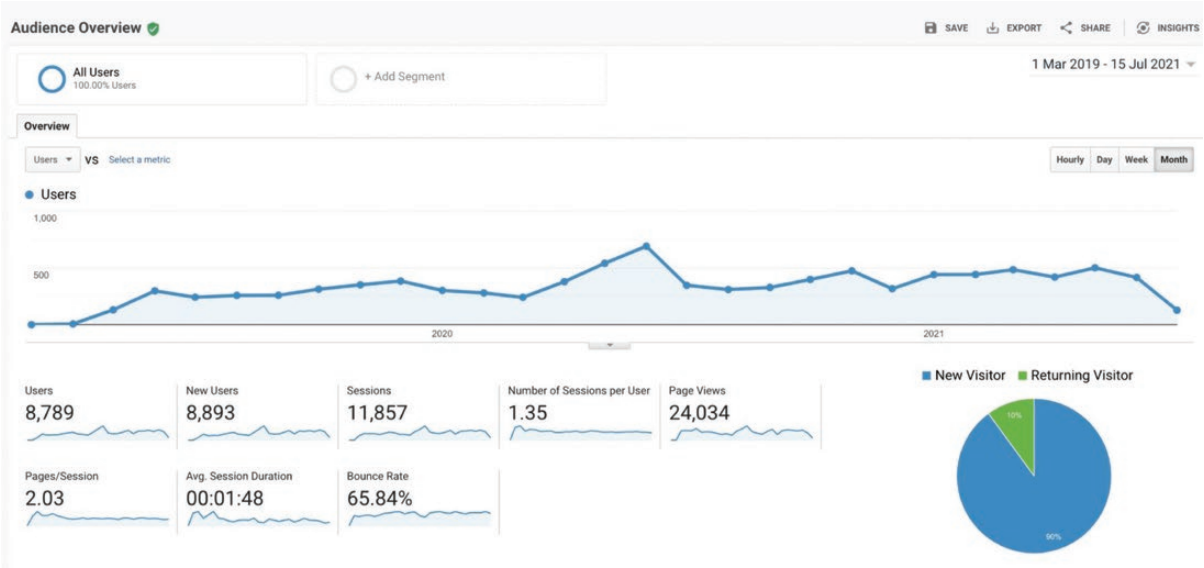

FIGURE 13 Early Youth Engagement-2 website activity throughout the intervention, with each point representing a month from March 2019 to July 2021. The tallest peak corresponds to the third months of the first national lockdown in June 2020.

> EA016: *'I suspect in our team sometimes if people have been really, really stretched and short staffed, some of the younger people may not have even progressed to the full face-to-face assessment, it might have been, you know, rejected at an earlier stage. I do wonder if our team has been a little bit stricter about some of the younger people that may be referred with hearing voices but not quite frequent enough to be taken on'.*
> L003: *'There is extra pressure on the service, the amount of referrals we have for the older age group . . . we haven't got corresponding staff for the extra so it was underestimated, the probably a quarter to a third more referrals'.*

Organisational framing

Organisational framing refers to the features of the clinical setting that promote or inhibit the intervention and its components from being put into practice. The organisational context in which much of the EYE-2 operated was one of acute pressure due to the impact of AWTS on caseload size, mix, severity and complexity and an influx of new staff, alongside massive disruption from COVID-19 which impacted on all aspects of service delivery, staff sickness and turnover.

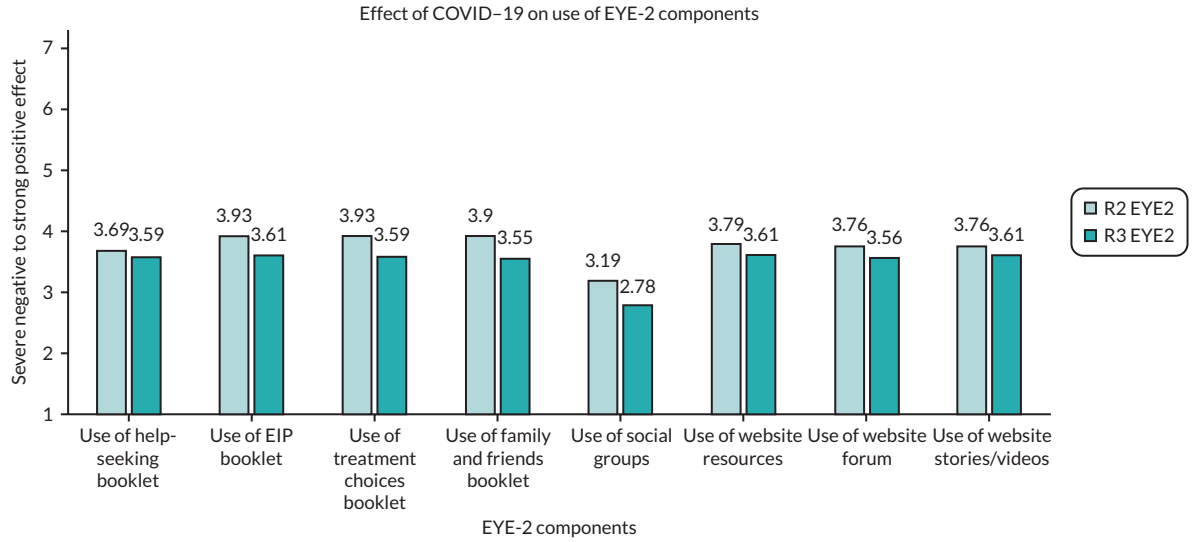

FIGURE 14 Effect of COVID-19 on use of a range of EYE-2 tools and components, from mid intervention (R2 *n* = 81) to end of the intervention (R3 *n* = 68), scores on a seven-point Likert scale (SDs R2:1.37; 1.33; 1.35; 1.28; 1.67; 1.26; 1.23; 1.28; R3: 1.18; 1.22; 1.26; 1.26; 1.57; 1.20; 1.23; 1.24).

Intervention components and strategies

It is in this context that the EYE-2 intervention was implemented. Implementation of the intervention components, strategies, rules, resources and procedures was influenced by the *organising logic of* (1) implementation capacity: organisational support, care co-ordinator caseload size and funding; (2) implementation context: geography, epidemiology (e.g. patient language and ethnicity), socioeconomic and sociocultural issues (e.g. deprivation, staff turnover, discharge management policies, EIP intake criteria), service user characteristics (e.g. risk, mental state) and (3) implementation execution processes. Space was not an issue as staff moved to remote working.

Implementation process mechanisms

This section describes how the intervention was enacted over time, through implementation mechanisms, drawing on training, and longitudinal quantitative and qualitative data. The training evaluation is described in *Appendix 5*, and a detailed evaluation of mechanisms involved in the early (round 1), middle (round 2) and late (round 3) stages of intervention delivery, with a full set of quotes in *Appendix 9*, *Tables 45–50* and *Figure 29*.

Coherence building

Two key processes involved in sense-making of the EYE-2 intervention over time were the extent to which EYE-2 was seen as different (differentiated) from standard EIP, and then how it was internalised and valued by individuals. From the outset, staff internalised the value in the approach. The training was experienced as helpful, and attitudes towards implementation were positive (see *Appendix 5*). Qualitatively, staff commented on the relevance of the training for their work: 'This is a great training that really does feel connected with the reality of EI practice'. One person commented that it was 'good to get back to values and focus on what is important'. The MI focus was viewed as helpful and different from usual practice by some, but more of a refresher for others, 'really helpful "top up"/reminder of skills around MI'.

In the early stages of EYE-2 delivery, the booklets, website and social groups were also differentiated from standard practice. The EYE-2 approach was valued for being consistent with the EIP ethos, and the resources for being professional, reliable, adapted for ethnic minorities, and instilling hope for recovery. Staff described that EYE-2 reminds, reassures and reinforces familiar approaches and skills. Communal specification was limited as EYE-2 was seen as aimed at individual care co-ordinators.

By the mid to end of the intervention, the additional value of EYE-2 was in the standardised approach, similar to existing practice, but encouraging staff to stay on track and build practices of sharing the resources with service users. The booklets were seen as a psychoeducational tool, providing critical information and reducing stigma. Some also differentiated the specific focus on individual goals and wider social networks as novel.

> M22: *'I think carers actually particularly seem to like [the booklets] and service users, because I think they like actually receiving something. So erm I think they've gone down well in that respect'.*
> M22: *'Well obviously working with EYE-2, the person-centred and individual care aspect of what we do isn't new but actually the standardised approach is beneficial. I do think it's beneficial . . . To sort of be able to provide standardised information that everybody is aware that's there'.*

For some, the internalised value of the intervention was in the impact it had on their own knowledge and skills.

> M28: *'I found it quite difficult to know what I was really doing coming into the EIP team. I think the books have helped me to confirm my information that I'm passing on to other people. And putting it in a way that's quite simplistic as well . . . because sometimes you can boggle people with terminology. So yeah, it's helped me to understand so I can have those discussion with people'.*

However, remembering the EYE-2 approach was a barrier to implementation (see *Appendix 9*, *Tables 45* and *46* for details of barriers and facilitators), which may have reflected a failure to internalise the intervention as valuable. While some staff clearly valued the approach and resources, others were not really sure what was required of them beyond handing out booklets and lacked understanding of requirements.

> TV21: *'It's not that we don't want to do it but you get so much stuff. If you get regular updates, reminders, you know, it just keeps it fresh on your mind because you forget.*
> M28: *We find caseloads are quite high. We find that we are losing the essence of an EI service because of that, and I think these things help us to remember'.*
> TV29: *'Just having [EYE-2 research assistant] presence reminds us'.*

Cognitive participation

Two key activities in implementation were enrolment in and legitimisation of EYE-2. Some staff enrolled in and legitimised EYE-2 during the training, bringing their own case studies, and taking value from the training network 'to gain insight into how other teams experience the same barriers in their practice, through discussion', and legitimising the work of engagement: 'I found the service users involvement particularly insightful of difficult experiences under EI and a snippet of the challenges they've had and what EI needs to be dealing with'.

EYE-2 was initially seen to be driven by new, young, creative, adventurous IT literate staff whose enthusiasm sparked further interest. New staff were 'inducted' through reading the booklets, which led to improvements in staff knowledge, and positive feedback from staff, service users and families legitimised the intervention.

> M22: *'I would provide it to students to say look this is us in a nutshell. For me it's part and parcel of meeting someone now I'll just take out the booklets'.*
> EA25: *'I think just actually reading through the booklets myself because actually when I joined the team that's what my manager gave me to read. It was quite helpful to kind of have a basis of what the team's about, things like that. I think they are kind of even good to give to staff sometimes. I don't think it's purely a thing that helps just the service users and families'.*

The responsibility for delivery thus shifted from team leaders to practitioners, supported by the EYE-2 RA, and from them to service users and families who were encouraged to enrol in the approach as a legitimate set of practices, and options visited and revisited.

> TV29: *'Having the booklets, is a really helpful format to go through the interventions that we offer and think about what's helpful to people, and to come back to it. It makes sure they've got the information at their fingertips rather than asking them to go away and kind of look things up. We could have an hour conversation and they've only taken in 10 minutes and it's nice to know they've got something they can go back to and reflect and revisit'.*

Mid-intervention, during the third national lockdown, there was some divergence in enrolment and legitimation. Older colleagues were less aware or did not find the approach helpful, and enrolment was challenging as informal staff discussions and observations were limited by remote working.

> TV21: *'We're not always in the office now. So, a lot of stuff that staff learnt is through discussions in the office, when people were asking what you were doing, or it would just come up in conversation'.*

Some clinicians did not use resources when clients lacked insight, were challenging to engage or were unaccepting of their diagnosis, or because the information was viewed as overwhelming. Some thought Zoom social groups were too intrusive, and some stopped promoting social groups which were poorly attended, thus limiting legitimation.

> EA25: *'In terms of people that lack capacity, I probably wouldn't have used a lot of the stuff. I normally wouldn't have used until they were feeling a bit better'.*

Some staff simply handed out resources, without incorporating them into the intervention approach, further undermining legitimation, and some became uncertain of the value over time. There was a tendency, rather than refer to the trial manual, resources or team structures for support, to revert to standard practice or to request more training.

> M33: *'In terms of the EYE-2 approach . . . I don't remember very much about the theoretical approach other than it matched entirely with what we were already doing. So there certainly hasn't been any resistance but at the same time there hasn't been any reason to change because it's been in line with what we've already been doing'.*

Further training was requested in 12 of the 21 interviews at mid and late therapy (see *Appendix 9*, *Table 46* outlines barriers to implementation). Whether a lack of internalisation of value, or an impact of increased workload pressure, there was a push for the trial team to be reminding and prompting, and providing more booster trainings.

Collective action

Key processes of the operational work involved in implementing EYE-2 were how to do the work (interactional workability) and the impact on confidence (relational integration).

The training provided guidance on how to do the work in relation to social groups, MI techniques and the value and use of the booklets and resources. Staff members said, 'thinking about barriers to implementing peer support groups' and 'discussion re: implementing social groups' were helpful, and 'the scenarios . . . [gave] us room to explore how MI would work in risk management'. Staff were given information on when and how to use the resources with service users and their social network to enhance engagement, but some staff requested 'more focus on how the booklets can be woven into engagement work'. Confidence in using a range of EYE-2 approaches increased from pre to post training (see *Chapter 5* and *Appendix 5*). For some, the desire for more training impacted on confidence, 'some additional time on motivational interviewing could have been helpful', while others were already confident with applying motivational and other techniques.

There was a lot of consideration about how and when to use the approach and resources (see *Appendix 9*), and clinicians developed a series of work arounds, with the onset of the pandemic, posting and e-mailing online copies of booklets and promoting the website.

> **TV29:** *'I use them at the beginning to give them the information about the service and go through them with them. I will give them the Likemind website, and to families as well because often they bombard you with questions, understandably the first time you meet them. Then sort of return to, you know before our CPA, have a read through our treatment booklet. See if there's anything there that we haven't covered that you think we should'.*
> **H26:** *'I sent a link to them in email because we've been using email a lot with the clients. I noticed that is something new, something changed'.*

However, rather than describing a learned skill set, staff described needing more training and reminders. Barriers also emerged in how to do the work with some saying they were unable to stock resources at home or access them in the office during lockdowns.

> **TV29:** *'One of the barriers for us with obviously home working, we actually have mostly lost our desks in the office, and I live in quite a small environment, so I don't particularly want to bring a bunch of booklets home with me'.*

At the end of the intervention, while many staff continued to consider how to deliver the intervention, some stopped promoting social group as they did not want patients to depend on something that may disappear. Staff appeared more confident in the resources which were seen to build trust, provide quality information and reduce the chance that patients felt overwhelmed. A few team leaders reminded clinicians about resources in supervision, as something that might make their job easier, but concerns were still raised about insufficient training and confidence in using MI approaches. Confidence ratings in using the EYE-2 approaches overall were similar to that found for using generic EIP approaches.

There were also no real impacts of the EYE-2 intervention on feelings of pride, role confidence and professionalism compared to that seen for EIP in general, where ratings were potentially slightly higher (*Figure 15*).

Reflexive monitoring

Reflexive monitoring is the appraisal of the intervention. COVID-19 had a negative impact on staff's perceived ability to engage young people, across both EYE-2 and EIP arms, as well as on their ability to use EYE-2 resources. These impacts were present from shortly after the onset of the pandemic and continued to impact 16 months later, at the end of the intervention.

Appraisal of the value of EYE-2 was mostly by individuals, in relation to the resources, and especially the treatment choices booklet, which were seen as valuable. Clinicians found positive feedback from peers, service user and families to be highly influential in encouraging further use. Some talked about social groups being needed and appealing to service users who looked forward to them.

> EA25: *'I've generally gotten good positive feedback and they do help with giving areas to focus on'.*
> TV29: *'People who engage really well see the benefit of them, really like the information. Maybe they engage more because they've had it, who knows. I've had a lot of good feedback from families. I don't think I've had a single family member say that they are not helpful'.*

Some clinicians stated that EYE-2 was not a priority during COVID-19, and that they were struggling to complete key tasks. Some reported using the booklets less often, and that memory remained a barrier.

> M22: *'It was crazy. I think it made us go into crisis mode. Now we've got through that it feels like we've got to try and resume some usual way of functioning. And it does feel like there's a lot to be . . . rebuilt because some things just have not taken priority. I think in terms of EYE-2, I suppose it maybe hasn't been a priority because, there's been a huge other thing to think about. It hasn't been just EYE-2 that's gone a little bit by the wayside'.*

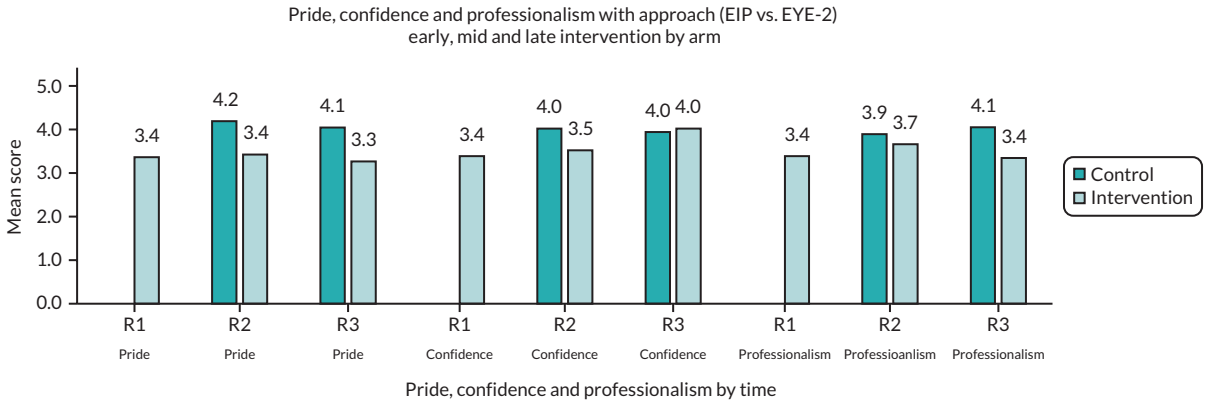

FIGURE 15 Total pride, role confidence and professionalism when using the EYE-2 resources compared to using generic EIP approaches at early, mid and end of the intervention. Scored on a five-point Likert scale. Note: Round 1 data were not available in the EIP arm [SDs: pride (EIP/EYE-2) R1:0.98; R2:0.74;0.88; R3:0.84; 1.02; confidence (EIP/EYE-2) R1:0.97; R2:0.77;0.91; R3:0.91; 1.1; professionalism (EIP/EYE-2) R1:0.88; R2:0.73;0.94; R3:0.86; 1.1].

COVID-19 impacted on the general mood in services and engagement with EYE-2, although some found that the EYE-2 RAs helped to keep EYE-2 in mind and some suggested reconfiguration of how they usually did things, to integrate the resources into practice and save time, leaving information with patients to go through independently.

At the end of EYE-2, the appraisal of the intervention was largely positive, based on informal feedback. Resources were described as professional, quality psychoeducational tools to challenge stigma and promote trust and confidence in EIP. In terms of reconfiguration, many clinicians described using the resources across their caseload, and some were concerned about losing the resources when the trial ended. However, some newer team members and managers without caseloads were less aware of EYE-2.

> **TV37:** *'[The booklets are] the first thing I give to care-coordinators to introduce them to it. It's actually quite nice for staff that are new to EIS, not only for patients, so I'm having a panic thinking oh no we are going to lose all this'.*

Despite COVID-19, implementation (*Figures 16* and *17*) was largely maintained across time, but there was no increase, and mean scores masked fluctuations with changes in COVID restrictions, staff mix and turnover.

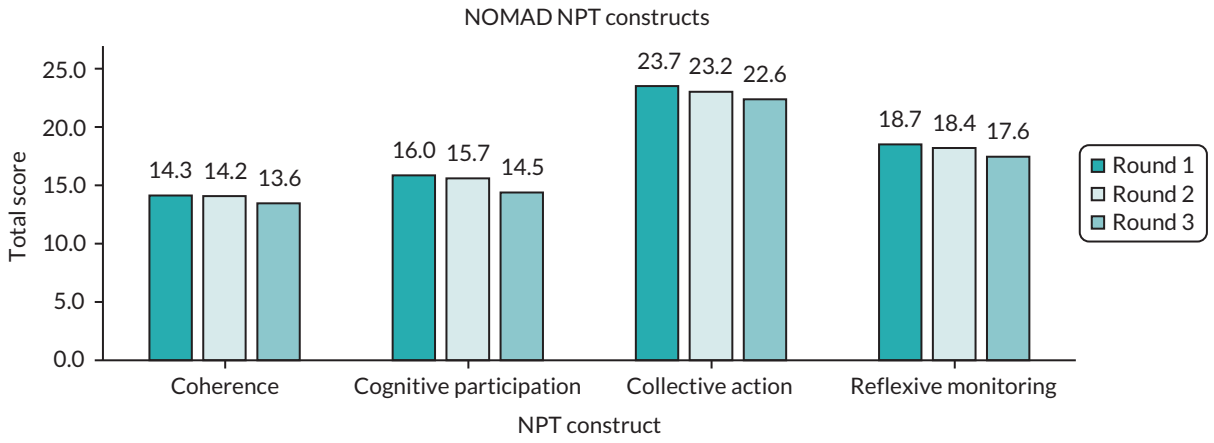

FIGURE 16 Mean NOMAD scores for coherence building (max score = 20), cognitive participation (max score = 20), collective action (max score = 35) and reflexive monitoring (max score = 25). (SDs: coherence: 2.3; 2.8; 2.8; cognitive participation 2.3; 2.4; 2.9; collective action: 3.3 3.9; 3.8; reflexive monitoring 2.5; 3.1; 3.6.)

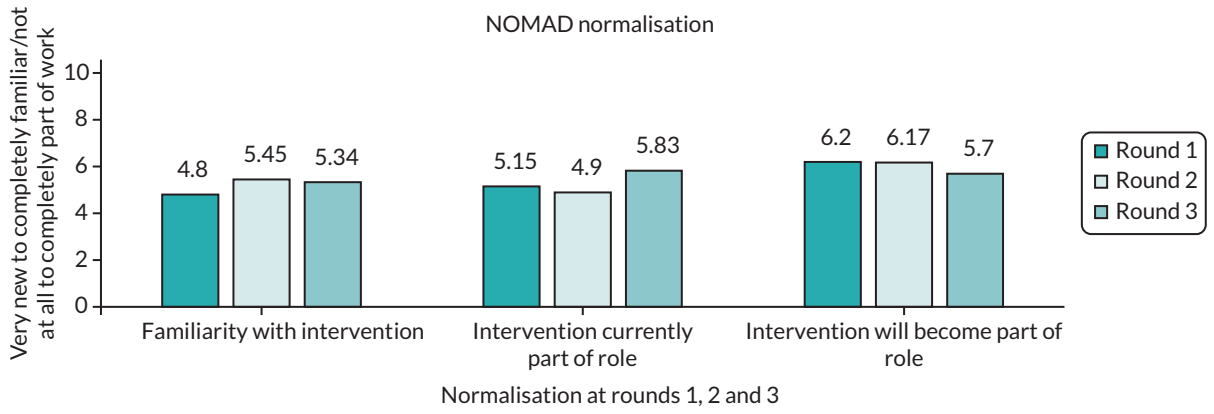

FIGURE 17 Intervention familiarity and the extent to which EYE-2 formed part of current and likely future work at early, mid and end of the intervention period. (SDs: familiarity: 2.25; 2.64; 3.02; current work: 2.15; 2.49; 3.01; future role 2.0; 2.48; 2.7.)

Implementation outcomes

Intervention performance

Intervention performance was assessed through a comparison of (1) use of *approaches* across both EYE-2 and EIP and (2) use of EYE-2 *resources* over time within the intervention.

There were no notable differences in the use of EYE-2 approaches across EIP and EYE-2 arms at mid and end of the intervention period. There was a slight tendency early in the intervention, for staff in the EYE-2 arm to listen to goals and plans and provide treatment choices and options to a higher proportion of their EYE-2 service users compared to EIP staff (*Figures 18* and *19*). These discussions may have been more relevant early in the engagement process, facilitated by use of the booklets and website which were well-used especially early in the intervention (e.g. *Figure 20*).

Relational restructuring

Therapeutic alliance and therefore relational restructuring did not differ between the EIP and EYE-2 arms over time, suggesting no changes in the therapeutic relationship due to EYE-2 (*Figure 21*). However, higher alliance in the intervention arm correlated positively with greater self-reported use of the EYE-2 intervention at the end of the trial (rho = 0.42, $p = 0.008$) and with greater use of EYE-2 resources at the start and end of the intervention. Therapeutic alliance also correlated with self-reported use of engagement approaches (motivational approaches, listening, openness,

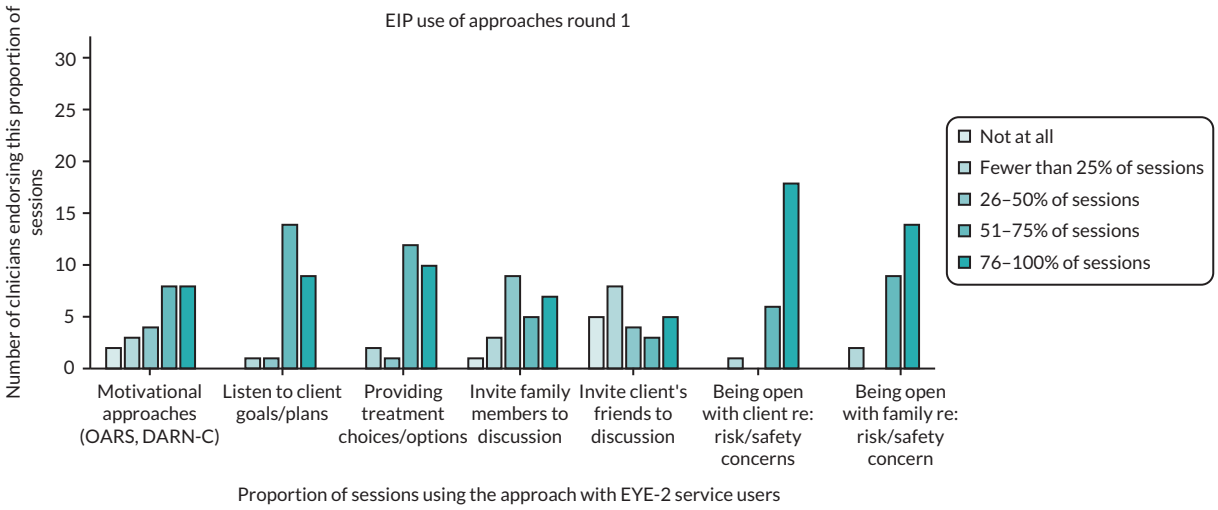

FIGURE 18 Use of approaches in round 1 for EIP.

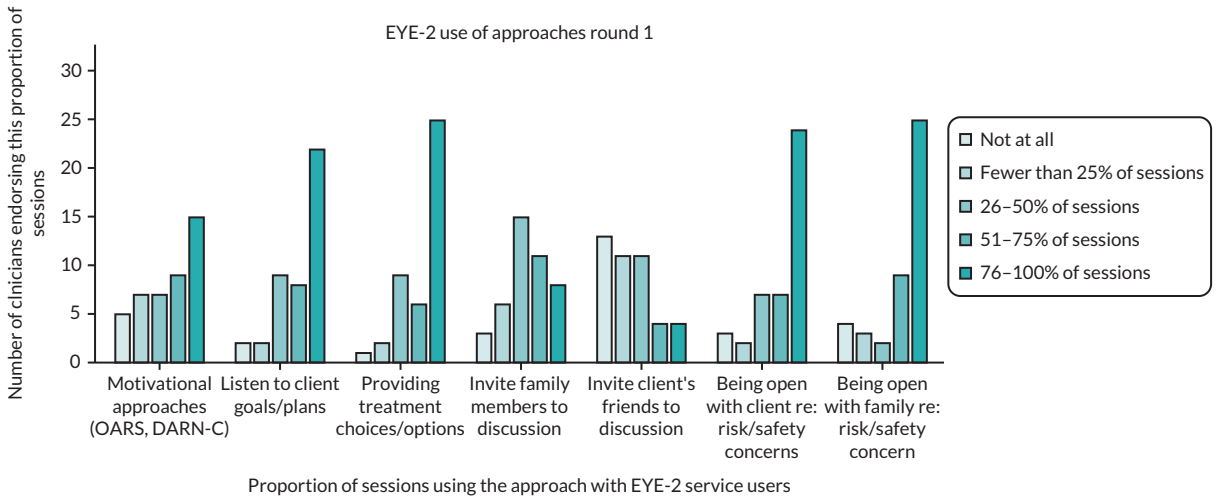

FIGURE 19 Use of approaches in round 1 for EYE-2.

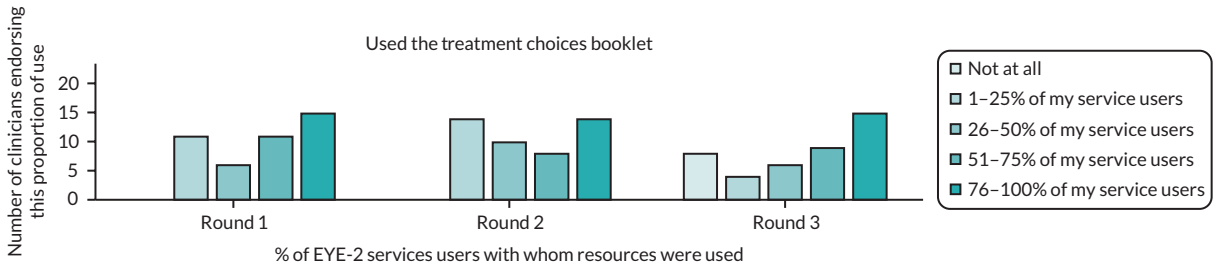

FIGURE 20 Use of the treatment choices booklet in the EYE-2 intervention over time.

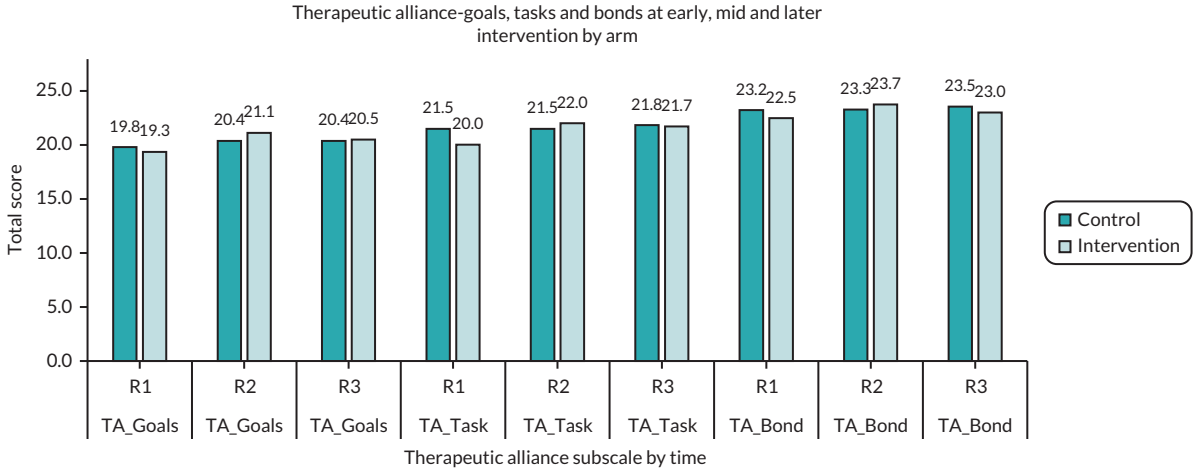

FIGURE 21 Therapeutic alliance scores for the working alliance inventory for goals, tasks and bonds across time (early mid and end of intervention) and between arms (EIP vs. EYE-2). SDs for goals (R1 3.2; 2.6 R2 3.2; 2.5; R3 3.1; 2.9); tasks (R1 12.6; 4.0; R2 2.9; 2.8 R3 3.1; 3.3) and bonds (R1 2.6; 3.4; R2 2.5; 1.9; R3 2.7; 2.7).

providing treatment choice, engaging family). So, although alliance was similar in both arms, EYE-2 clinicians were more likely to use EYE-2 resources and approaches to support their relational work with their patients.

Normative restructuring

Six additional contextual factors were rated for their impact on delivery on Likert scales ranging from 1 (severe negative) to 7 (strong positive) impact. A score of 4 equalled no impact.

In general, these factors had limited impact on EYE-2 approaches, with the most negative impact being the patients' reading ability. Means and SDs were as follows: team perspectives [mean (SD) R1 3.76 (1.02); and R2 4.14 (0.84)], service user insight [mean (SD) R1 3.64 (1.05); and R2 4.21 (1.20)], service user reading ability [mean (SD) R1 3.56 (0.89); and R2 3.60 (1.06)], service user feedback [mean (SD) R1 3.89 (0.96); and R2 4.34 (1.10)], clinician's own familiarity [mean (SD) R1 3.55 (1.27); and R2 4.31 (1.20)] and clinician's own confidence in EYE-2 approaches [mean (SD) R1 3.66 (1.27); and R2 4.40 (1.17)].

Normalisation (sustainability)

Intervention familiarity and the extent to which the intervention was part of current work increased slightly over time, indicating a modest degree of normalisation, although use of the intervention dropped slightly at the onset of COVID-19 (see *Figure 17*). Ratings were slightly higher for the likelihood that the intervention would form part of future work, indicating a modest degree of sustainability although this dropped at the end, possibly because the project was finishing.

The data collection training as an intervention

Experience of the data collection training was also positive. Confidence and beliefs about the importance of collecting outcome data both increased from pre to post training [for confidence, $b = 1.33$, $t(268.47) = 15.94$, $p < 0.001$ and for

importance, $b = 0.78$, $t(268.74) = 11.85$, $p < 0.001$]. On average, staff reported a high likelihood of collecting outcome data following training. Clinicians described increased coherence and sense-making, through individual and communal specification of the requirements, purpose and value of data collection. One staff member said the training '. . . give[s] some meaning/purpose to completing the measures instead of going through the motions'. Another said: 'I've worked in my team for two years and this is the first time anyone has bothered to talk to me about them'. However, this was not a view shared by everyone, with another staff member saying: '[Trust name] have been using the measures for years so teams are familiar with this'. Staff appreciated 'reflecting on the clinical value of the QPR and DIALOG' and valued 'ideas about positively using QPR and DIALOG to inform care plans'. There were indications of enhanced initiation, legitimation, and reflexive monitoring in appraising data collection as worthwhile. Staff felt that use of the measures could enhance therapeutic alliance 'using the DIALOG as a tool for building a therapeutic relationship', and engagement 'I have an improved understanding of the outcome measurement tools and how they can be used to improve patients' engagement with care delivery'. Interactional workability increased as staff described that the 'opportunity for discussion around barriers and solutions to implementing measures' and the 'attractive user-friendly manual' and 'resources for creating graphs to compare questionnaire data' were helpful.

Contamination

Contamination was minimal, with only two instances of use of the EYE-2 booklets, two of use of the website and three instances of use of the manual mid-way through the trial.

Discussion

In terms of context, the *strategic intention* was to provide a minimally disruptive and supportive framework of tools (booklets, website, social groups) and approaches (motivational and systemic alliance and psychoeducation), to support staff to better engage young people. These tools and approaches were optimally supported by a care co-ordinator introducing and discussing these, although some were able to use the resources alone or with family. *The adaptive execution* meant that staff understood the focus on individual goals and family support and that using the resources promoted engagement, but COVID-19 had a substantial impact on engagement across both EIP and EYE-2 teams. Reductions in F2F contact made engagement harder for everyone. It was harder to hand out booklets which were sometimes inaccessible in offices, or to work with patients and their families, and social groups stopped completely, before restarting online or by phone. Some of the impacts of COVID-19 on EYE-2 teams may have been ameliorated slightly through use of the EYE-2 website which increased substantially during the first lockdown. *Negotiated capacity* was substantially impacted by COVID-19. Restrictions on contact undoubtedly hollowed out the EYE-2 intervention, de-prioritising the therapeutic value of social networks and social groups. Many teams were impacted by workload pressures linked to AWTS, which further affected capacity. Many teams adopted more stringent criteria for accepting patients into services, which changed the nature of the EIP caseload. Patients with more mild symptoms, and those who were harder to engage in initial assessments were less likely to be accepted and those who were taken on were more likely to have a schizophrenia-spectrum diagnosis. The organisational logic for EYE-2 was one of acute pressure due to the impact of AWTS on caseload size, mix, severity and complexity, an influx of new staff, and massive disruption from COVID-19 which impacted all aspects of service delivery.

In terms of processes, coherence was characterised by a differentiation of EYE-2 as a standardisation of practice, and the use of the booklets as valued psychoeducational tools for staff, families and service users. There was limited understanding of requirements and purpose beyond this. Cognitive participation processes were focused on enrolment and legitimation. Both new staff and patients were inducted into the approach which was legitimised through positive feedback. However, remote working reduced opportunities for enrolment, and some staff set limits on use of the approaches with their service users which reduced legitimation. Collective action processes included examples of how to do the work, and confidence in using the approach, and more specifically the booklets and resources. There was less focus on how to build a therapeutic alliance or use motivational approaches. Despite the need identified in the implementation models for organisational support, this contextual integration was severely limited. Reflexive monitoring was largely related to positive appraisals and feedback.

The overarching pattern was of heterogeneity and fluctuation in implementation, with both facilitators and barriers in operation. There was a constant pressure to adapt, and this was at its peak mid-trial, in the context of multiple national lockdowns. While some staff developed creative workarounds, others struggled to manage core tasks. Staff were working remotely, and there was limited opportunity to learn from and support each other. Organisational support was limited as team and clinical leads were focused on meeting AWTS and on the changing service demands because of COVID-19. EYE-2 champions changed due to staff turnover, or were hard to reach, and their role in modelling EYE-2 implementation was limited by remote working.

The process evaluation confirmed that both COVID-19 and AWTS impacted on delivery of EYE-2. Modest levels of implementation were maintained, but there was no progression of implementation over time. In terms of potential mechanisms of change, there was limited capacity for an impact via social network support, due to the impact of COVID-19 on social contact. There was limited capacity for an impact via therapeutic alliance, as this aspect of the intervention was less well understood and was undoubtedly affected by the reduction in F2F contact. There was no difference in therapeutic alliance over time or between the EYE-2 and EIP teams, although in the EYE-2 arm, use of the booklets did correlate with a stronger therapeutic alliance. This may have meant that using the booklets enabled clinicians to build a stronger alliance, or that those who were better at using the booklets were also better at building a therapeutic alliance.

The greatest potential for impact was via psychoeducational processes. Use of the booklets was generally well-received and positively appraised. Psychoeducation has been recognised in psychosis and EIP services as an intervention in its own right, with impacts on engagement (compliance) with treatment approaches, relapse, re-admission, social and global outcomes.[80,81] However, there were wide variations in approaches to psychoeducation. While some people used the resources to shape sessions and care plans, and revisit treatment choices and goals, others simply handed out the booklets. It seems likely that a robust psychoeducation approach was used by a subgroup of staff, with a subgroup of patients, influenced by patient characteristics and opportunities post COVID. Qualitative feedback suggests that the booklets were more likely to be used to benefit service users who were already better engaged, with more insight, and a more stable mental state, and for whom there may have been limited scope to improve engagement. The opportunity to use the resources F2F may have been limited to those with a higher risk mental state who were seen in person, where the resources may have offered a language to communicate about risk and prevent or reduce crises. The outcome data collection training was seen as an intervention in its own right, which had the potential to enhance care planning, goal focus and engagement.

There are several limitations to this evaluation. The quantitative data comprised a subset of clinicians and data were neither fully independent nor a single cohort over time. Inferential statistics were not conducted. The qualitative samples were convenience samples which may have been more positive about EYE-2. The evaluation nevertheless provides valuable information with which to aid the interpretation of results.

Chapter 8 Discussion

Summary of the results

Study strengths

One strength of this study was the whole population sample of *all* 1027 FEP patients who were allocated to a care co-ordinator in 1 of 20 EIP teams in England over a 14-month period, and who were followed up for 12–26 months. A second strength was the multifaceted development process for the intervention and resources, which were adapted for LGBTQ and ethnic minorities including for those whose first language is not English, and a third strength is the substantial PPI input throughout the entire project which shaped the intervention, delivery, evaluation and dissemination.

Patient and public involvement

Chapter 2 outlined the embedded multilevel PPI approach to this project, impacts and outcomes including adapted tools, the co-produced social group booklet, and blogs on the McPin website.

Model development

Chapter 3 outlined the development of the implementation toolkit, and the intervention and implementation models. Three pathways to outcome were proposed via systemic/family support, therapeutic alliance/motivational behaviour change and psychoeducation mechanisms.[76–81,167]

Equality, diversity and inclusion

Chapter 4 described the qualitative ethnic and LGBTQ diversity study and the resulting adaptations to the EYE-2 implementation toolkit, booklets, manuals, training programme and intervention to enable it to better meet the needs of young people from a diversity of backgrounds to engage and feel included and understood.

Effectiveness evaluation

Chapter 5 described the effectiveness study which revealed no effect of the intervention on time to disengagement or on any of the secondary mental health, QoL or recovery outcomes, A&E contacts or nights spent in hospital, and no evidence that COVID-19, substance use, symptoms, education, ethnicity, deprivation or caseload size affected findings. Possible explanations for the lack of differences between arms were proposed which included:

- Lower than expected rates of disengagement which were at 16% in each arm, meaning there was limited room for further reduction on the primary outcome.
- Comparatively short follow-up times (12 months) for some participants which further reduced the possibility of disengagement.
- Stringent disengagement definitions which lowered the identified disengagement.
- Stringent definitions of FEP and acceptance to caseload, so that, unlike in the EYE pilot project where disengagement included those who struggled to engage at assessment and those with milder presentations who disengaged due to lack of need rather than mutual agreement, the EYE-2 population potentially comprised a more severe schizophrenia-spectrum sample who were more assertively engaged.
- Differential missing data on the secondary outcomes for those who disengaged, which meant that there was limited opportunity to capture any effects of the intervention on mental health, recovery or QoL after someone had disengaged.
- The choice of secondary outcome measures, which were routinely used in EIP services and presented the best opportunity for collecting data on people who were disengaging. Our intervention logic model, based on our previous qualitative studies identified a different set of intermediate outcomes. It remains possible that utilising measures that addressed these outcomes would have revealed greater change.
- Higher quality teams with improved service provision and outcomes in both arms due to the implementation of the AWTS.[33]

- The possibility that the data collection training and support, and the enhanced collection and use of data comprised an active intervention that also promoted engagement.
- The COVID-19 pandemic which impacted on likely patterns of engagement and disengagement and on intervention delivery.
- The planned whole population intervention approach being too broad and therefore ineffective. A more targeted approach directed at those at higher risk of disengagement may have had a better outcome.
- Or finally, the EYE-2 model may simply be articulating a good quality Early Intervention in Psychosis service approach, which is already delivered.

Health economic evaluation

Chapter 6 comprised the health economic evaluation. Across the whole sample, there was an indication of lower mean cost of mental healthcare utilisation, after accounting for intervention costs, in the intervention arm. This reflected lower costs for unplanned admissions, crisis and Mental Health Act assessments.

- This was a cost-saving for the intervention of −£788 (95% CI −£3571 to £1994) with a probability of 28.8% that the total mental health system costs would be higher for intervention trial participants.
- A cost-effectiveness analysis carried out from a mental healthcare provider perspective indicated a 43.4% probability that the EYE-2 intervention dominated usual care (lower total cost and superior outcome).
- There was also an indication that mean total societal cost was lower in the intervention arm with a cost-saving in the intervention arm of −£526 per participant (−£7031 to £5980) and a probability of 43% that this would be higher in the intervention arm.
- In a subset of 22% of the sample, who consented and completed an interview about societal costs after 12 months, the EYE-2 intervention was associated with:
    - 5.73 more days spent in stable, independent living (95% CI −1.79 to 13.25) with the probability of a positive outcome for the intervention of 98%;
    - 7.56 more days spent in paid or unpaid employment (95% CI −35.64 to 50.76) with the probability of a positive outcome for the intervention of 77%; and
    - 30 more days spent in education and training (95% CI 1.52 to 53.68) with the probability of a positive outcome for the intervention of 99%.

Confidence in the societal findings was substantially limited by uncertainty over the representativeness of the subsample who were studied.

Process evaluation

Finally, *Chapter 7* comprised the mixed-methods longitudinal process evaluation and outlined the context, processes and outcomes of implementation. There was evidence of widespread disruption due to COVID-19 and impacts of AWTS on caseload pressures and caseload mix such that only likely schizophrenia-spectrum cases were accepted. Further support was provided for the hypotheses that patients in the EYE-2 study were more likely to have schizophrenia-spectrum diagnoses and were a different population from the original EYE project. There was also some indication that the data collection training and support may have been an intervention in its own right, which also promoted engagement and better mental health outcomes.

Implementation processes were highly heterogeneous and fluctuating in use, with both facilitators and barriers in operation and a constant pressure to adapt to the changing context. Some staff developed creative workarounds, while others struggled to manage core tasks following the onset of the pandemic. Staff were working remotely, and there was limited opportunity to learn from and support each other. Organisational support was minimal as clinical and team leads were focussed on meeting AWTS and the changing service demands because of COVID-19. While a modest level of implementation was maintained, there was no real progression in implementation over time, and the EYE-2 intervention was only partially implemented. Two of the three mechanisms of change (systemic support and therapeutic alliance) were disrupted by COVID. Consistent with this, there were no differences in therapeutic alliance over time or between the EYE-2 and EIP teams.

The most likely active mechanism for change was via psychoeducational processes. The booklets and website were very well-received, used in structured ways and positively appraised by both staff, service users and carers. Use of the resources was associated with a stronger focus on therapeutic bonds, goals and tasks in the EYE-2 arm. They were used to promote knowledge and understanding of the EIP approaches, of psychosis, and of recovery and enabled a focus on a broader range of treatment approaches and goals. The lack of impact on engagement or mental health outcomes might have been because the psychoeducation focus alone was insufficient to achieve change, although psychoeducation has been shown to impact on compliance, relapse, re-admission, social and global outcomes in psychosis and from first episode.[82] It might have been because the outcomes were not the best or most sensitive to detect change as a result of psychoeducation, and that intermediate outcomes such as self-management, hope, resilience or empowerment may have been more appropriate.

Finally, it might have been that the planned whole population intervention approach was too broad and that a more targeted approach directed at a population that was most at risk of disengagement may have led to a better outcome. There is some support for this possibility as there was variation in approaches to psychoeducation. It seems possible that the EYE-2 psychoeducation approach and resources were more likely to be used with either:

- patients who were more clinically risky, and so required F2F contact during the pandemic, for whom the approach could be used in a way that was closer to what was intended. This group may have benefitted from accessing and discussing the resources in person, which offered a language to communicate about risk. This may in turn have explained the reduced unplanned service cost in a subgroup that had more need for crisis support in EYE-2, which was then captured by the more sensitive cost measures; or
- service users who were already better engaged, with more insight, a more stable mental state, and who may have been better able to make use of VC. These patients may have had more limited scope to improve engagement and mental health recovery but may also have been more likely to complete the health economic questionnaire and to benefit from the psychoeducation and goal focus to improve their vocational outcomes.

Integration and interpretation of findings

Why did the intervention fail to deliver change?

Fidelity to the intervention and coronavirus disease-19

The first major issue is fidelity to and implementation of the intervention. The process evaluation revealed that overall fidelity was low; on average clinicians reported using the resources with approximately half their patients. While there were some instances of high fidelity, with clinicians reporting use of booklets with most or all of their patients, there were more instances of limited to no use over the preceding 6 months. For the intervention to be effective, we would expect clinicians to be using the resources with most, or all of their patients, but this only happened in some teams and only at some time points. Only a subsample of 25–30% of arguably more engaged clinicians completed the process evaluation questionnaires, and one might expect that fidelity was lower in those who did not complete the questionnaires. Fidelity was harder to evaluate and deliver for soft skills, such as therapeutic engagement and motivational approaches. Indeed, the process evaluation revealed that while booklets were widely used there was 'less emphasis on motivational approaches' despite this being a key component of the intervention, and there was a lack of difference between the EYE-2 and EIP arms on engagement process measures such as therapeutic alliance. In the original EYE project, fidelity was higher, possibly because the intervention originated in the pilot site and staff buy-in was high. Use of booklets was highly correlated with reduced disengagement. Thus, a key explanation for the lack of impact of the intervention on engagement was that the intervention was not implemented as planned, and a key factor in this low fidelity was COVID-19. Nearly all teams (83%) decreased in fidelity to the intervention following the start of the pandemic. This is not surprising given the significant limitations in F2F contact, travel and working lives, which limited F2F contact with patients, and access to physical resources and rendered contact with family members, peers and social groups non-existent. Fidelity was not as high as planned initially, but qualitative data show a major deleterious effect of COVID-19. It is difficult to be sure, how the trial results may have differed in the absence of a global pandemic.

In terms of limitations, fidelity was assessed only through self-report in a subset of clinicians. Other options for an independent rating of fidelity were considered, such as taped sessions, control of access to and use of resources, but were ruled out due to the level of resource and buy-in required from teams and individuals, and the real possibility that this would discourage teams and individuals from taking part. However, the approach taken does not yield a full evaluation of implementation of intervention processes within study.

Low rates of disengagement and generalisation to the rest of the United Kingdom

The second big factor with implications for the findings was the lower-than-expected rate of disengagement. Our expected rate of disengagement of 25% was based on the systematic review by Doyle *et al.*,[34] which found a mean disengagement rate of 30% and our own EYE project pre-intervention rate of 24%. The systematic review was not limited to the UK or to EIP services, but the one UK-based study reported disengagement rates of 40%. However, we found 16% disengagement, close to our target rate for the EYE-2 intervention of 15%, in both arms of the study. This did not leave much room for further reduction. We have now conducted our own meta-analysis which found similar rates of 17% disengagement.[126] In this review we limited studies to EIP services, but only one study was based in the UK. That study[134] reported disengagement of 11% but was based on data from only one, largely rural service, using a less rigorous definition of disengagement that excluded people where there was a 'mutually agreed' discharge (which was very high at 51%), or the person moved out of area or left the country. Disengagement was not double rated so no data were available on reliability of the disengagement rating, and our own research suggests that some discharges and moves out of area were due to disengagement, so it seems plausible that Solmi and colleagues may have underestimated disengagement. There are no other UK-based studies with which to compare our findings, and indeed our own study, comprising approximately 10% of the entire new EIP population in a 14-month period, likely provides the most definitive estimate of true disengagement rates from current EIP services in the UK.

But why such a low rate? Are Early Youth Engagement-2 trusts high performing?

The services we selected to take part in the project may have been from higher performing trusts in England that were not representative of the UK as a whole given that we selected large, stand-alone teams, with a research-active regional lead and that teams were situated in the North-West (two trusts), East (two trusts), London (two trusts) and South-East (three trusts) of England, but not the South-West, Midlands, Yorkshire or the North-East. However, we did explicitly sample across geographies and urban and rural environments; we did make invite teams via regional leads in all EIP regions and included less commonly researched teams, for example Great Yarmouth. Furthermore, a comparative analysis of the performance of the nine trusts involved in the study against all trusts (n = 55) nationally through the NCAP for 2020–1 did not support the claim that these were selectively high-performing. NCAP data were collected between September and November 2020, mid-way through our trial, and trusts were compared against standards for waiting times, and access to NICE-recommended interventions including CBT, family interventions, clozapine, employment support, physical health screening and interventions and carer support. The data showed that EYE-2 trusts were fairly evenly distributed across all other trusts in the UK, with individual trusts ranking between 2nd and 50th, and 37–78% of EYE-2 trusts sitting in the top half of all trusts depending on the standard assessed (see *Appendix 10*, *Table 51*). EYE-2 trusts were not high performing compared to other trusts across the UK, and overall, it seemed that our EIP teams were representative of teams across the country. Our disengagement rate is thus likely a good indication of the true rate of disengagement across the UK.

What impact have Access and Waiting Time Standards had on the Early Intervention in Psychosis patient population?

An alternative explanation to the lower-than-expected disengagement rate is that the NHS England AWTS led to better-quality care in both arms of the EYE-2 project and a change in the nature of the populations served by EIP teams since these standards were implemented in 2016, which in turn influenced engagement. Since the original EYE project was conducted, there has been substantial investment in EIP services nationally, leading to increases in the number and skill mix of staff, and expectations that FEP service users within EIP services will be allocated to a care co-ordinator within 2 weeks of first presentation and offered the full range of NICE guidelines interventions. This is likely to have enabled teams to better engage with their service uses, thus leading to reduced disengagement. However, these expectations have also led to challenges in terms of capacity to meet demand in some services, resulting in the application of more stringent acceptance criteria for FEP, and reduced acceptance of people with early patterns of disengagement and diagnostic uncertainty. The potential impact of this is that a subgroup of patients who are harder

to engage and where diagnosis is less apparent initially are rejected from EIP services until they present in an inpatient setting. This scenario is supported by the extremely low acceptance rates in some services (e.g. 8% of referrals) and the high proportion of patients within EYE-2 with at least one inpatient admission (42%). The low disengagement rate may thus in part reflect the fact that some of those prevented from disengaging in the original EYE project are simply no longer accepted into services unless they are later present in an inpatient setting.

And did low disengagement affect the Early Youth Engagement-2 findings?

The low level of disengagement did make it harder to demonstrate an impact of EYE-2. We expected to reduce disengagement from 25% to 15%, but the rate of disengagement was already at 16% making any further reduction unlikely, regardless of the effectiveness of the EYE-2 intervention, and this may have contributed to the lack of effects. The EYE-2 intervention was not effective on any of the other secondary mental health or QoL outcome measures either, but differential missing data for those who disengaged impacted our ability to fully evaluate these outcomes. It seems likely that the low disengagement rate partially, but not fully explains the lack of EYE-2 effect on disengagement.

Whole population and whole staff group approach

The final plausible factor which may have impacted the results, was the whole population approach and whole staff group approach. It is possible that clinicians did not deliver the intervention to all their clients because the intervention was relevant to certain subgroups only. These subgroups were at opposite ends of the engagement spectrum, comprising those at greatest risk of disengagement and hospitalisation where engagement was critical, and those who were very well engaged but might especially benefit from the holistic targeted motivational and psychoeducational approach. There is some support for this in the health economic findings, which revealed benefits from EYE-2 in terms of social and occupational outcomes for a well-engaged subgroup who consented and completed the societal impact questionnaire. EYE-2 may have been more effective if targeted at specific subgroups by specific clinicians, who were trained on induction into the service and were motivated and committed to delivering the approach.

Research recommendations

1. More UK-based research should be conducted to replicate and validate rates and predictors of disengagement from EIP services in UK populations including the North-East, South-West and Midlands regions.
2. More research should be undertaken of the impact that migration and social isolation have on young people's mental health.
3. Future research should focus on two main participant groups:

    a. Patients with FEP in inpatient and crisis settings where experiences are often negative and dictate their pattern of engagement for years to come.
    b. Patients who are well engaged may benefit from a psychoeducational approach targeted at positive social and occupational outcomes and supported by the EYE-2 resources as psychoeducational and self-help tools.

Implications for clinical practice

Clinical implications arising out of this work are as follows:

1. It would appear that Early Intervention services are now much less likely than previously to work with diagnostic uncertainty, hard to reach and itinerant populations. The nature of EIP services has changed, with the potential that more people will again present for the first time in an inpatient setting. We should take more steps to reengage these populations.
2. The number of young people living and moving across the country away from close family was high. It is possible as identified by Craig Morgan and colleagues[121,122] that some young people struggle with migration within the UK, becoming more socially isolated and at risk for psychosis. We should consider how to better support our young people with their mental health when they are living away from home in universities and other settings.

3. Staff may be much more likely to adopt innovative new practices if inducted into these when they first join the service, or if they are involved in developing the innovation themselves from the ground up. We should consider in future how to develop intervention approaches that can be adapted and tailored for each individual team as part of a bottom-up process while also maintaining fidelity to the core approach.
4. Clinical EIP staff valued having the high-quality patient-centred EYE-2 resources at their fingertips to support their engagement with selective patients. We should ensure that all EIP teams can access and use these resources in the future.
5. Both patients and family members expressed that they would like to see an approach of this sort targeted specifically towards staff engagement in in-patient settings. This is a key priority for patients and their families, as many people told us that their initial inpatient experiences shaped their future engagement intentions over the long term.

Dissemination

Objective 6 was to disseminate widely through the study website; peer-reviewed papers; service user publications; conference presentations; VLOGs; tweet chats; co-ordinated press releases; national networks and NHS England. Despite the lack of impact on the primary and secondary outcomes beyond what is delivered in standardised EIP, the booklets, resources and engagement model provide a valuable resource with which to guide best practice in EIP service delivery. We have already commenced this work with peer-reviewed papers in preparation, published service user blogs, VLOGs, films already recorded, and tweet chats planned. Our recent presentation with NHS England (19 July 2022) to EIP service leads nationally confirmed that access to the booklets and website resources was desirable. Of those attending the webinar in real time, all wanted copies of the booklets for their services and 94% wanted them in both print and online form (see *Appendix 10*, *Figure 30*). Attendees wanted a range of support to aid them in using the resources including videos to watch and discuss, the printed implementation packs, and an interactive training session (see *Appendix 10*, *Figure 31*). The implementation toolkit is now ready to support dissemination. We have produced a series of six VLOGs to tell people about the trial and to introduce the resources, their value and uses, including for people with diversity. Finally, a word cloud captured clinician's thought about the resources and the central role for psychoeducation (see *Appendix 10*, *Figure 32*).

Conclusion

There were no effects of the intervention on any of the primary or secondary effectiveness outcomes. The intervention may have been cost-effective in reducing mental health and societal cost due to reduced use of unplanned crisis care, and tentatively in improved vocational outcomes in a subsample. Wide CIs and non-negligible probabilities of observing findings that are counter to this mean these findings should be treated cautiously. COVID had a substantial impact on implementation of the EYE-2 intervention: fidelity to the intervention was low across multiple teams and time points, and Access and Waiting Time Standards led to both improved quality of standard EIP service delivery and changes in the EIP population during the trial, which likely impacted results. The intervention was most likely delivered as a standardised psychoeducational tool by a subsample of clinicians to a subsample of patients. The approach may work best in terms of effectiveness in future if targeted at those most open to psychoeducational approaches or those most at risk of disengagement or crises. Qualitative feedback revealed that the resources and psychoeducation approach were highly valued by clinicians, service users and families. Taken together, the resources and engagement model for lead practitioners may constitute an important toolkit to support and standardise best practice in EIP.

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Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

Ethical approval was granted for this study through London Dulwich Research. Ethics Committee IRAS Project ID 238744 REC Reference 18/LO/0362 on 10 May 2018.

Information governance statement

Sussex Partnership NHS Foundation Trust (SPFT) is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, SPFT is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here *https://www.sussexpartnership.nhs.uk/our-services/using-our-services/your-experience-patient/confidentiality*.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/WDWG4102.

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References

1. Sartorius N, Jablensky A, Korten A, Ernberg G, Anker M, Cooper JE, Day R. Early manifestations and first-contact incidence of schizophrenia in different cultures. A preliminary report on the initial evaluation phase of the WHO Collaborative Study on determinants of outcome of severe mental disorders. *Psychol Med* 1986;**16**:909–28.
2. Department of Health. *The NHS Plan. A Plan for Investment. A Plan for Reform*. London: The Stationery Office; 2000 (Cm. 4818-I).
3. Rössler W, Salize HJ, van Os J, Riecher-Rössler A. Size of burden of schizophrenia and psychotic disorders. *Eur Neuropsychopharmacol* 2005;**15**:399–409.
4. Parks J, Svendsen D, Singer P, Foti ME, editors. *Morbidity and Mortality in People with Serious Mental Illness*. Alexandra, VA: National Association of State Mental Health Program Directors (NASMHPD), Medical Directors Council; 2006.
5. Wiersma D, Nienhuis FJ, Slooff CJ, Giel R Natural course of schizophrenic disorders: a 15-year followup of a Dutch incidence cohort. *Schizophr Bull* 1998;**24**:75–85.
6. Bertelsen M, Jeppesen P, Petersen L, Thorup A, ∅hlenschlæger J, Quach PL, *et al.* Suicidal behaviour and mortality in first-episode psychosis: the OPUS trial. *Br J Psychiatry* 2007;**191**:s140–6.
7. Birchwood M, Todd P, Jackson C. Early Intervention in Psychosis: the critical period hypothesis. *Br J Psychiatry Suppl* 1998;**172**:53–9.
8. Birchwood M, Fiorillo A. The critical period for early intervention. *Psychiatr Rehabil Skills* 2000;**4**:182–98.
9. Bottlender R, Sato T, Jäger M, Wegener U, Wittmann J, Strauss A, Möller H-J. The impact of duration of untreated psychosis prior to first psychiatric admission on the 15-year outcome in schizophrenia. *Schizophr Res* 2003;**62**:37–44.
10. Pelosi AJ, Birchwood M. Is early intervention for psychosis a waste of valuable resources? *Br J Psychiatry* 2003;**182**:196–8.
11. Mihalopoulos C, Harris M, Henry L, Harrigan S, McGorry P. Is Early Intervention in Psychosis cost-effective over the long term? *Schizophr Bull* 2009;**35**:909–18.
12. Harris MC, Henry LP, Harrigan SM, Purcell R, Schwartz OS, Farrelly SE, *et al.* The relationship between duration of untreated psychosis and outcome: an eight-year prospective study. *Schizophr Res* 2005;**79**:85–93.
13. The IRIS Initiative. URL: www.iris-initiative.org.uk/practitioner-learning/practitioner-learninghome/specialistlearning-resources/iris-guidelines-/iris-guidelines-principles (accessed 15 August 2022).
14. Harris MG, Burgess PM, Chant DC, Pirkis JE, McGorry PD. Impact of a specialized early psychosis treatment programme on suicide. Retrospective cohort study. *Early Interv Psychiatry* 2008;**2**:11–21.
15. Marshall M, Lewis S, Lockwood A, Drake R, Jones P, Croudace T. Association between duration of untreated psychosis and outcome in cohorts of first-episode patients: a systematic review. *Arch Gen Psychiatry* 2005;**62**:975–83.
16. Perkins DO, Gu H, Boteva K, Lieberman JA. Relationship between duration of untreated psychosis and outcome in first-episode schizophrenia: a critical review and meta-analysis. *Am J Psychiatry* 2005;**162**:1785–804.
17. Drake RJ, Lewis SW. Early detection of schizophrenia. *Curr Opin Psychiatry* 2005;**18**:147–50.
18. Melle I, Larsen TK, Haahr U, Friis S, Johannessen JO, Opjordsmoen S, *et al.* Reducing the duration of untreated first-episode psychosis: effects on clinical presentation. *Arch Gen Psychiatry* 2004;**61**:143–50.
19. Melle I, Johannesen JO, Friis S, Haahr U, Joa I, Larsen TK, *et al.* Early detection of the first episode of schizophrenia and suicidal behavior. *Am J Psychiatry* 2006;**163**:800–4.

20. Pinfold V, Smith J, Shiers D. Audit of Early Intervention in Psychosis service development in England in 2005. *Psychiatr Bull* 2007;**31**:7–10.
21. Lester H, Birchwood M, Bryan S, England E, Rogers H, Sirvastava N. Development and implementation of early intervention services for young people with psychosis: case study. *Br J Psychiatry* 2009;**194**:446–50.
22. Joseph R, Birchwood M. The national policy reforms for mental health services and the story of early intervention services in the United Kingdom. *J Psychiatry Neurosci* 2005;**30**:362–5.
23. McGorry PD, Edwards J, Mihalopoulos C, Harrigan SM, Jackson HJ. EPPIC: an evolving system of early detection and optimal management. *Schizophr Bull* 1996;**22**:305–26.
24. Bertolote J, McGorry P. Early intervention and recovery for young people with early psychosis: consensus statement. *Br J Psychiatry Suppl* 2005;**48**:s116–9.
25. DOH. *National Service Framework for Mental Health: Modern Standards and Service Models*. 1999. URL: www.gov.uk (accessed 18 February 2023).
26. DOH. *The National Plan: A Plan for Investment a Plan for Reform*. 2000. URL: https://webarchive.nationalarchives.gov.uk/ukgwa/20130107105354/; www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_118522.pdf (accessed 18 February 2023).
27. DOH. *Priorities and Planning Framework 2003–2006*. 2003. URL: www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAnd GuidanceArticle/fs/en?CONTENT_ID=4008430&chk= IXp8vH (accessed October 2015).
28. DOH. *Improvement, Expansion and Reform – the Next 3 Years: Priorities and Planning Framework 2003–2006*. 2006. URL: http://image.guardian.co.uk/sys-files/Society/documents/2002/10/02/improvementexpansionreform.pdf (accessed 18 February 2023).
29. DOH. *EI Recovery Plan*. 2006. URL: (accessed 1 January 2018).
30. DOH. *The NHS in England: Operating Framework for 2007–08*. 2007. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/243293/7093.pdf (accessed 18 February 2023).
31. DOH. *The NHS in England: Operating Framework for 2008–09*. 2008. URL: https://depositedpapers.parliament.uk/?Terms=The+NHS+in+England%3A+Operating+Framework+for+2008%E2%80%9309.&OrderBy=Relevance&DepositedFrom=&DepositedTo=&House=All&DepartmentSesId=&Expanded=False (accessed 18 February 2023).
32. DOH. *New Horizons: A Shared Vision for Mental Health*. 2009. URL: www.nhs.uk (accessed 18 February 2023).
33. NHS England, the National Collaborating Centre for Mental Health and the National Institute for Health and Care Excellence. *Implementing the Early Intervention in Psychosis Access and Waiting Time Standard: Guidance*. 2016. URL: nice.org.uk (accessed 15 August 2022).
34. Doyle R, Turner N, Fanning F, Brennan D, Renwick L, Lawlor E, Clarke M. First episode psychosis and disengagement from treatment: a systematic review. *Psychiatr Serv* 2014;**65**:603–11.
35. Turner M, Smith-Hamel C, Mulder R. Prediction of twelve-month service disengagement from an Early Intervention in Psychosis service. *Early Interv Psychiatry* 2007;**1**:276–81.
36. Conus P, Lambert M, Cotton S, Bonsack C, McGorry PD, Schimmelmann BG. Rate and predictors of service disengagement in an epidemiological first-episode psychosis cohort. *Schizophr Res* 2010;**118**:256–63.
37. Krstev H, Carbone S, Harrigan S, Curry C, Elkins K, McGorry P, *et al.* Early intervention in first-episode psychosis – the impact of a community development campaign. *Soc Psychiatry Psychiatr Epidemiol* 2004;**39**:711–9.
38. Cotton SM, Lambert M, Schimmelmann BG, Foley DL, Morley KI, McGorry PD, Conus P. Gender differences in premorbid, entry, treatment, and outcome characteristics in a treated epidemiological sample of 661 patients with first episode psychosis. *Schizophr Res* 2009;**114**:17–24.

39. Polari A, Berk M, MacNeil C, Conus P. Duration of untreated psychosis: what are we talking about? *Acta Neuropsychiatrica* 2009;**21**:106–8.

40. Malla A, Norman R, McLean T, Scholten D, Townsend L. A Canadian programme for early intervention in non-affective psychotic disorders. *Aust N Z J Psychiatry* 2003;**37**:407–13.

41. Turner MA, Boden JM, Smith-Hamel C, Mulder RT. Outcomes for 236 patients from a 2-year Early Intervention in Psychosis service. *Acta Psychiatr Scand* 2009;**120**:129–37.

42. Schimmelmann BG, Conus P, Schacht M, McGORRY P, Lambert M. Predictors of service disengagement in first-admitted adolescents with psychosis. *J Am Acad Child Adolesc Psychiatry* 2006;**45**:990–9.

43. Conus P, Cotton S, Schimmelmann BG, McGorry PD, Lambert M. The first-episode psychosis outcome study: premorbid and baseline characteristics of an epidemiological cohort of 661 first-episode psychosis patients. *Early Interv Psychiatry* 2007;**1**:191–200.

44. Greenwood K, Berry C, Labuschagne K, Chandler R, Peters E, de Visser R, *et al.* Facilitating engagement and hope to protect against social disability: the Early Youth Engagement (EYE) project and beyond. *Schizophr Bull* 2015;**41**:s174.

45. Greenwood K, Chandler R, Labuschagne K, Peters E, Alford K, de Visser R, *et al*. The development and piloting of an Early Youth-Engagement (EYE) model to improve engagement of young people in first episode psychosis services: a mixed methods study. *Early Interv Psychiatry* 2025 Jan;**19**(1):e13623. https://doi.org/10.1111/eip.13623. Epub 2024 Oct 22. PMID: 39435971.

46. Berry C, Greenwood K. Hope-inspiring therapeutic relationships, professional expectations, and social inclusion for young people with psychosis. *Schizophr Res* 2015;**168**:153–60.

47. Greenwood K, Webb R, Gu J, Fowler D, de Visser R, Bremner S, *et al.* The Early Youth Engagement in first episode psychosis (EYE-2) study: pragmatic cluster randomised controlled trial of implementation, effectiveness and cost-effectiveness of a team-based motivational engagement intervention to improve engagement. *Trials* 2021;**22**:272. https://doi.org/10.1186/s13063-021-05105-y

48. Nordentoft M, Jeppesen P, Abel M, Kassow P, Petersen L, Thorup A, *et al.* OPUS study: suicidal behavior, suicidal ideation and hopelessness among patients with first-episode psychosis. *Br J Psychiatry* 2002;**181**:s98–106.

49. Nordentoft M, Jeppesen P, Petersen, Thorup A, Ohlenschlaeger J, Krarup G, *et al*. The OPUS trial: a randomized multicentre trial of integrated versus standard treatment for 547 first-episode psychotic patients. *Schizophr Res* 2004;**70**:31.

50. Craig TK, Garety P, Power P, Rahaman N, Colbert S, Fornells-Ambrojo M, Dunn G. The Lambeth Early Onset (LEO) Team: randomised controlled trial of the effectiveness of specialised care for early psychosis. *BMJ* 2004;**329**:1067.

51. Garety PA, Craig TK, Dunn G, Fornells-Ambrojo M, Colbert S, Rahaman N, *et al.* Specialised care for early psychosis: symptoms, social functioning, and patient satisfaction. *Br J Psychiatry* 2006;**188**:37–45.

52. Dodgson G, Crebbin K, Pickering C, Mitford E, Brabban A, Paxton R. Early Intervention in Psychosis service and psychiatric admissions. *Psychiatr Bull* 2008;**32**:413–6.

53. Tait L, Birchwood M, Trower P. Predicting engagement with services for psychosis: insight, symptoms, and recovery style. *Br J Psychiatry* 2003;**182**:123–8.

54. Royal College of Psychiatrists. *Early Intervention in Psychosis Network Self-Assessment Tool Guidance*. College Centre for Quality Improvement. London: Royal College of Psychiatrists; 2016.

55. NHS England. *NHS England investment in mental health 2015/16*. 2014. URL: www.england.nhs.uk/wp-content/uploads/2014/11/payment-systs-mh-note.pdf (accessed 15 August 2022).

56. The Schizophrenia Commission. *The Abandoned Illness: A Report from the Schizophrenia Commission*. 2012. URL: www.rethink.org/media/2637/the-abandoned-illness-final.pdf (accessed 18 February 2023).

57. McCrone P, Craig T, Power P, Garety P. Cost-effectiveness of an early intervention service for people with psychosis. *Br J Psychiatry* 2010;**196**:377–82.

58. McCrone P, Knapp M. Economic evaluation of early intervention services. *Br J Psychiatry* 2007;**191**:s19–22.

59. Knapp M, Andrew A, McDaid D, Iemmi V, McCrone P, Park A, *et al. Investing in Recovery: Making the Business Case for Effective Interventions for People with Schizophrenia and Psychosis*. London: London School of Economics and Political Science: Centre for Mental Health and Department of Health; 2014.

60. Tsiachristas A, Thomas T, Leal J, Lennox BR. Economic impact of Early Intervention in Psychosis services: results from a longitudinal retrospective controlled study in England. *BMJ Open* 2016;**6**:e012611.

61. Anderson KK, Fuhrer R, Schmitz N, Malla AK. Determinants of negative pathways to care and their impact on service disengagement in first-episode psychosis. *Soc Psychiatry Psychiatr Epidemiol* 2012;**48**:125–36.

62. Stowkowy J, Addington D, Liu L, Hollowell B, Addington J. Predictors of disengagement from treatment in an early psychosis program. *Schizophr Res* 2012;**136**:7–12.

63. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, *et al.* GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *Res Involv Engagem.* 2017;**3**:13.

64. Wing JK, Beevor AS, Curtis RH, Park SB, Hadden S, Burns A. Health of the Nation Outcome Scales (HoNOS). Research and development. *Br J Psychiatry* 1998;**172**:11–8. https://doi.org/10.1192/bjp.172.1.11

65. Neil ST, Kilbride M, Pitt L, Nothard S, Welford M, Sellwood W, Morrison AP. The questionnaire about the process of recovery (QPR): A measurement tool developed in collaboration with service users. *Psychosis* 2009;**1**:145–55. https://doi.org/10.1080/17522430902913450

66. Priebe S, Golden E, McCabe R, Reininghaus U. Patient-reported outcome data generated in a clinical intervention in community mental health care – psychometric properties. *BMC Psychiatry* 2012;**12**:113. https://doi.org/10.1186/1471-244X-12-113

67. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, *et al.* Process evaluation of complex interventions: medical research council guidance. *BMJ* 2015;**350**:h1258.

68. Ling T. Evaluating complex and unfolding interventions in real time. *Evaluation* 2012;**18**:79–91.

69. Greenhalgh T, Papoutsi C. Studying complexity in health services research: desperately seeking an overdue paradigm shift. *BMC Med* 2018;**16**:95.

70. Anderson LM, Petticrew M, Rehfuess E, Armstrong R, Ueffing E, Baker P, *et al.* Using logic models to capture complexity in systematic reviews. *Res Synth Methods* 2011;**2**:33–42.

71. Greenwood-Lee J, Hawe P, Nettel-Aguirre A, Shiell A, Marshall DA. Complex intervention modelling should capture the dynamics of adaptation. *BMC Med Res Methodol* 2016;**16**:51.

72. Mills T, Lawton R, Sheard L. Advancing complexity science in healthcare research: the logic of logic models. *BMC Med Res Methodol* 2019;**19**:55. https://doi.org/10.1186/s12874-019-0701-4

73. Rohwer A, Pfadenhauer L, Burns J, Brereton L, Gerhardus A, Booth A, *et al.* Logic models help make sense of complexity in systematic reviews and health technology assessments. *J Clin Epidemiol* 2016;**83**:37–47. https://doi.org/10.1016/j.jclinepi.2016.06.012

74. May CR, Mair F, Finch T, MacFarlane A, Dowrick C, Treweek S, *et al.* Development of a theory of implementation and integration. *Implement Sci* 2009;**4**:29.

75. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101.

76. Seikkula J, Trimble D. Healing elements of therapeutic conversation: dialogue as an embodiment of love. *Fam Process* 2005;**44**:461–75.

77. Razzaque R, Wood L. Open dialogue and its relevance to the NHS: opinions of NHS staff and service users. *Community Ment Health J* 2015;**51**:931–8.

78. Harrop C, Ellett L, Brand R, Lobban F. Friends interventions in psychosis: a narrative review and call to action. *Early Interv Psychiatry* 2015;**9**:269–78.

79. Bowman S, Alvarez-Jimenez M, Wade D, Howie L, McGorry P. The positive and negative experiences of caregiving for siblings of young people with first episode psychosis. *Front Psychol* 2017;**8**:730. https://doi.org/10.3389/fpsyg.2017.00730

80. McGorry PD. Psychoeducation in first-episode psychosis: a therapeutic process. *Psychiatry* 1995;**58**:313–28. https://doi.org/10.1080/00332747.1995.11024736

81. Xia J, Merinder LB, Belgamwar MR. Psychoeducation for schizophrenia. *Cochrane Database Syst Rev* 2011;**2011**:CD002831. https://doi.org/10.1002/14651858.CD002831.pub2

82. Marwaha S, Thompson A, Upthegrove R, Broome MR. Fifteen years on–early intervention for a new generation. *Br J Psychiatry* 2016;**209**:186–8.

83. Mascayano F, van der Ven E, Martinez-Ales G, Henao AR, Zambrano J, Jones N, *et al.* Disengagement from early intervention services for psychosis: a systematic review. *Psychiatr Serv* 2021;**72**:49–60.

84. Royal College of Psychiatrists Centre for Quality Improvement. *Early Intervention in Psychosis Network Self-Assessment Tool Guidance*. London: Centre for Mental Health and Department of Health; 2016.

85. Morgan C, Fearon P, Lappin J, Heslin M, Donoghue K, Lomas B, *et al.* Ethnicity and long-term course and outcome of psychotic disorders in a UK sample: The ÆSOP-10 study. *Br J Psychiatry* 2017;**211**:88–94. https://doi.org/10.1192/bjp.bp.116.193342

86. Kline E, Thomas L. Cultural factors in first episode psychosis treatment engagement. *Schizophr Res* 2018;**195**:74–5. https://doi.org/10.1016/j.schres.2017.08.035

87. Memon A, Taylor K, Mohebati LM, Sundin J, Cooper M, Scanlon T, de Visser R. Perceived barriers to accessing mental health services among black and minority ethnic (BME) communities: a qualitative study in Southeast England. *BMJ Open* 2016;**6**:e012337. URL: https://bmjopen.bmj.com/content/6/11/e012337 (accessed 11 February 2024).

88. Islam Z, Rabiee F, Singh S. Black and minority ethnic groups' perception and experience of Early Intervention in Psychosis services in the United Kingdom. *J Cross Cult Psychol* 2015;**46**:737–53.

89. Rathod S, Kingdon D, Phiri P, Gobbi M. Developing culturally sensitive cognitive behaviour therapy for psychosis for ethnic minority patients by exploration and incorporation of service users' and health professionals' views and opinions. *Behav Cogn Psychother.* 2010;**38**:511–33. https://doi.org/10.1017/S1352465810000378

90. Rathod S, Graves E, Kingdon D, Thorne K, Naeem F, Phiri P. Cultural Adaptations in Clinical InteractiONs (CoACtION): a multi-site comparative study to assess what cultural adaptations are made by clinicians in different settings. *Int Rev Psychiatry* 2020;**33**:3–15. https://doi.org/10.1080/09540261.2020.1750818

91. Kidd SA, Howison M, Pilling M, Ross LE, McKenzie K. Severe mental illness among LGBT populations: a scoping review. *Psychiatr Serv* 2016;**67**:779–83.

92. Heck JE, Sell RL, Gorin SS. Health care access among individuals involved in same-sex relationships. *Am J Public Health* 2006;**96**:1111–8.

93. McCann E, Sharek D. Survey of lesbian, gay, bisexual, and transgender people's experiences of mental health services in Ireland. *Int J Ment Health Nurs* 2014;**23**:118–27.

94. McDermott E, Roan K. *Queer Youth, Suicide and Self-Harm: Troubled Subjects, Troubling Norms*. Hampshire: Palgrave McMillan; 2016.

95. Rathod S, Kingdon D, Pinninti N, Turkington D, Phiri P. *Cultural Adaptation of CBT for Serious Mental Illness: A Guide for Training and Practice*. Chichester: Wiley-Blackwell; 2015.

96. Rathod S, Phiri P, Harris S, Underwood C, Thagadur M, Padmanabi U, Kingdon D. Cognitive behavioural therapy for psychosis can be adapted for minority ethnic groups: a randomised controlled trial. *Schizophr Res* 2013;**143**:319–26.

97. Naeem F, Gul M, Irfan M, Munshi T, Asif A, Rashid S, *et al.* Brief culturally adapted CBT (caCBT) for depression: a randomized controlled trial from Pakistan. *J Affect Disord* 2015;**177**:101–7.

98. Naeem F, Saeed S, Irfan M, Kiran T, Mehmood N, Gul M, *et al.* Brief culturally adapted CBT for psychosis (CaCBTp): a randomized controlled trial from a low-income country. *Schizophr Res* 2015;**164**:143–8.

99. Li W, Zhang L, Luo X, Liu B, Liu Z, Lin F, *et al.* A qualitative study to explore views of patients', carers' and mental health professionals' to inform cultural adaptation of CBT for psychosis (CBTp) in China. *BMC Psychiatry* 2017;**17**:131. https://doi.org/10.1186/s12888-017-1290-6

100. Rathod S, Phiri P, Naeem F. An evidence-based framework to culturally adapt cognitive behavioural therapy. *Cogn Behav Ther* 2019;**12**:1–15.

101. Alvidrez J, Azocar F, Miranda J. Demystifying the concept of ethnicity for psychotherapy researchers. *J Consult Clin Psychol* 1996;**64**:903–8.

102. National Institute of Health Research. *Trial Forge INCLUDE Ethnicity Framework*. 2020. URL: www.trialforge.org/trial-forge-centre/include/ (accessed 15 August 2022).

103. Public Health England. *Producing Modelled Estimates of the Size of the Lesbian, Gay and Bisexual (LGB) Population of England*. London: PHE; 2017.

104. Jones CI, Bremner S, Hooper R, Gu J, Bartl G, Greenwood K. Statistical analysis plan for the Early Youth Engagement in first episode psychosis (EYE-2) study: a pragmatic cluster randomised controlled trial of implementation, effectiveness and cost-effectiveness of a team-based motivational engagement intervention to improve engagement. *Trials* 2021;**22**:732. https://doi.org/10.1186/s13063-021-05670-2

105. Gamble C, Krishan A, Stocken D, Lewis S, Juszczak E, Dore C, *et al.* Guidelines for the content of statistical analysis plans in clinical trials. *JAMA* 2017;**318**:2337–43.

106. Bertolote J, McGorry P. Early intervention and recovery for young people with early psychosis: consensus statement. *Br J Psychiatry* 2005;**187**:s116–9.

107. Bird V, Premkumar P, Kendall T, Whittington C, Mitchell J, Kuipers E. Early intervention services, cognitive–behavioural therapy and family intervention in early psychosis: systematic review. *Br J Psychiatry* 2010;**197**:350–6.

108. Future NHS. *Early Intervention in Psychosis Triangulation Tool*. URL: https://future.nhs.uk/system/login?nextURL=%2Fconnect%2Eti%2FEIPtriangulationtool%2Fview%3Fexp%3Dc1%26objectId%3D13093520 (accessed 15 August 2022).

109. Sealed Envelope Ltd. *Simple Randomization Service*. URL: www.sealedenvelope.com/simple-randomiser/v1/ (accessed 17 June 2021).

110. Stata Corp. *Stata Statistical Software: Release 14*. College Station, TX: Stata Corp LP; 2015.

111. Stata Corp. *Stata Statistical Software: Release 16*. College Station, TX: Stata Corp LLC; 2019.

112. Campbell MK, Piaggio G, Elbourne DR, Altman DG; CONSORT Group. Consort 2010 statement: extension to cluster randomised trials. *BMJ* 2012;**345**:e5661.

113. McLennan D, Noble S, Noble M, Plunkett E, Wright G, Gutacker N. *The English Indices of Deprivation 2019: Technical Report*. Ministry of Housing, Communities and Local Government; 2019. URL: https://dera.ioe.ac.uk/id/eprint/34259/1/IoD2019_Technical_Report.pdf (accessed 11 February 2024).

114. Heß S. Randomization inference with Stata: a guide and software. *Stata J* 2017;**17**:630–51.

115. Twisk J, Bosman L, Hoekstra T, Rijnhart J, Welten M, Heymans M. Different ways to estimate treatment effects in randomised controlled trials. *Contemp Clin Trials Commun* 2018;**10**:80–5.

116. Little RJ, D'Agostino R, Cohen ML, Dickersin K, Emerson SS, Farrar JT, *et al.* The prevention and treatment of missing data in clinical trials. *N Engl J Med* 2012;**367**:1355–60.

117. White IR, Horton NJ, Carpenter J, Pocock SJ. Strategy for intention to treat analysis in randomised trials with missing outcome data. *BMJ* 2011;**342**:d40.

118. Wood AM, White IR, Thompson SG. Are missing outcome data adequately handled? A review of published randomized controlled trials in major medical journals. *Clin Trials* 2004;**1**:368–76.

119. Morris TP, Kahan BC, White IR. Choosing sensitivity analyses for randomised trials: principles. *BMC Med Res Methodol* 2014;**14**:11.

120. Gillard S, Bremner S, Patel A, Goldsmith L, Marks J, Foster R, *et al.*; ENRICH Trial Study Group. Peer support for discharge from inpatient mental health care versus care as usual in England (ENRICH): a parallel, two-group, individually randomised controlled trial. *Lancet Psychiatry* 2022;**9**:125–36.

121. Morgan C, Charalambides M, Hutchinson G, Murray RM. Migration, ethnicity, and psychosis: toward a sociodevelopmental model. *Schizophr Bull* 2010;**36**:655–64. https://doi.org/10.1093/schbul/sbq051

122. Gayer-Anderson C, Morgan C. Social networks, support and early psychosis: a systematic review. *Epidemiol Psychiatr Sci* 2013;**22**:131–46. https://doi.org/10.1017/S2045796012000406

123. Williams J, Leamy M, Pesola F, Bird V, Le Boutillier C, Slade M. Psychometric evaluation of the Questionnaire about the Process of Recovery (QPR). *Br J Psychiatry* 2015;**207**:551–5. https://doi.org/10.1192/bjp.bp.114.161695

124. Priebe S, Golden E, McCabe R, Reininghaus U. Patient-reported outcome data generated in a clinical intervention in community mental health care - psychometric properties. *BMC Psychiatry* 2012;**12**:113. URL: www.biomedcentral.com/1471-244X/12/113 (accessed 11 February 2024).

125. Fowler D, Hodgekins J, Howells L, Millward M, Ivins A, Taylor G, *et al.* Can targeted early intervention improve functional recovery in psychosis? A historical control evaluation of the effectiveness of different models of early intervention service provision in Norfolk 1998–2007. *Early Interv Psychiatry* 2009;**3**:282–8. https://doi.org/10.1111/j.1751-7893.2009.00146.x

126. Robson E, Greenwood K. Rates and predictors of disengagement and strength of engagement for people with a first episode of psychosis using early intervention services: a systematic review of predictors and meta-analysis of disengagement rates. *Schizophr Bull Open* 2022;**3**:sgac012. https://doi.org/10.1093/schizbullopen/sgac012

127. National Clinical Audit of Psychosis (NCAP) | Royal College of Psychiatrists. URL: rcpsych.ac.uk (accessed 15 August 2022).

128. NHS England. *Early Intervention in Psychosis – Elearning for Healthcare*. URL: e-lfh.org.uk (accessed 15 August 2022).

129. Liberati E, Richards N, Willars J, Scott D, Boydell N, Parker J, Jones PB. A qualitative study of experiences of NHS mental healthcare workers during the Covid-19 pandemic. *BMC Psychiatry* 2021;**21**:1–12.

130. Foye U, Dalton-Locke C, Harju-Seppanen J, Lane R, Beames L, Vera San Juan N, *et al.* How has COVID-19 affected mental health nurses and the delivery of mental health nursing care in the UK? Results of a mixed-methods study. *J Psychiatr Ment Health Nurs* 2021;**28**:126–37.

131. Sussex Partnership NHS Trust. *Learning for the Future Report on Staff Remote and Digital Working*. URL: www.sussexpartnership.nhs.uk/application/files/8516/6990/2530/our_response_to_covid19_-_remote_working_report_-_final_25-02-21.pdf (accessed 11 February 2024).

132. Sussex Partnership NHS Trust. *Learning for the Future Report on Staff Remote and Digital Working*. URL: www.sussexpartnership.nhs.uk/application/files/5316/6990/2524/0461_sussex_partnership_nhs_service_user_experiences_report.pdf (accessed 11 February 2024).

133. House of Commons Library. *Coronavirus: A History of English Lockdown Laws*. URL: https://commonslibrary.parliament.uk/research-briefings/cbp-9068/ (accessed 15 August 2022).

134. Solmi F, Mohammadi A, Perez JA, Hameed Y, Jones PB, Kirkbride JB. Predictors of disengagement from Early Intervention in Psychosis services. *Br J Psychiatry* 2018;**213**:477–83.

135. Holt RIG, Gossage-Worrall R, Hind D, Bradburn MJ, McCrone P, Morris T, *et al.* Structured lifestyle education for people with schizophrenia, schizoaffective disorder and first-episode psychosis (STEPWISE): randomised controlled trial. *Br J Psychiatry* 2019;**214**:63–73. https://doi.org/10.1192/bjp.2018.167

136. Gaughran F, Stahl D, Ismail K, Greenwood K, Atakan Z, Gardner-Sood P, *et al.*; IMPaCT Team. Randomised control trial of the effectiveness of an integrated psychosocial health promotion intervention aimed at improving health and reducing substance use in established psychosis (IMPaCT). *BMC Psychiatry* 2017;**17**:413. https://:doi.org/10.1186/s12888-017-1571-0

137. Montero-Marin J, Allwood M, Ball S, Crane C, De Wilde K, Hinze V, *et al.* School-based mindfulness training in early adolescence: what works, for whom and how in the MYRIAD trial? *Evid Based Ment Health* 2022;**25**:117–24.

138. Pitt L, Kilbride M, Nothard S, Wellford M, Morrison AP. Researching recovery from psychosis: a user-led project. *Psychiatr Bull* 2007;**31**:55–60. https://doi.org/10.1192/pb.bp.105.008532

139. Davidson L, Tondora J, Ridgway P. Life is not an 'outcome': reflections on recovery as an outcome and as a process. *Am J Psychiatr Rehabil* 2010;**13**:1–8. https://doi.org/10.1080/15487760903489226

140. NHS England. *Mental Health Clustering Booklet*. URL: https://assets.publishing.service.gov.uk/media/5a80099ded915d74e33f812d/Annex_B4_Mental_health_clustering_booklet.pdf (accessed 11 February 2024).

141. NHS Digital. *Reference Costs 2019/20*. URL: https://www.england.nhs.uk/publication/2019-20-national-cost-collection-data-publication/ (accessed 20 November 2024).

142. Husereau D, Drummond M, Augustovski F, de Bekker-Grob E, Briggs AH, Carswell C, *et al.* Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) statement: updated reporting guidance for health economic evaluations. *BMC Med* 2022;**20**:23.

143. Byford S, Harrington R, Torgerson D, Kerfoot M, Dyer E, Harrington V, *et al.* Cost-effectiveness analysis of a home-based social work intervention for children and adolescents who have deliberately poisoned themselves. Results of a randomised controlled trial *Br J Psychiatry* 1999;**174**:56–62.

144. Curtis L, Burns A. *Unit Costs of Health and Social Care 2020*. URL: www.pssru.ac.uk/project-pages/unit-costs/unit-costs-of-health-and-social-care-2021/ (accessed 10 June 2022).

145. Self R, Rigby A, Leggett C, Paxton R. Clinical decision support tool: a rational needs-based approach to making clinical decisions. *J Ment Health* 2008;**17**:33–48.

146. *Mental Health Clustering Tool and Initial Assessment Algorithm*. URL: https://assets.publishing.service.gov.uk/media/5a7b8ec8e5274a7318b8f708/Mental-Health-clustering-support-tool-algorithm.pdf (accessed 11 February 2024).

147. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M; Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655.

148. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, *et al.* A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021;**374**:n2061.

149. Pfadenhauer LM, Rohwer A, Burns J, Booth A, Lysdahl KB, Hofmann B, *et al. Guidance for the Assessment of Context and Implementation in Health Technology Assessments and Systematic Reviews of Complex Interventions: The Context and Implementation of Complex Interventions Framework*. Universitat Bremen: INTEGRATE-HTA; 2016. URL: www.researchgate.net/publication/298340571_Guidance_for_the_Assessment_of_Context_and_Implementation_in_Health_Technology_Assessments_HTA_and_Systematic_Reviews_of_Complex_Interventions_The_Context_and_Implementation_of_Complex_Interventions_C#fullTextFileContent (accessed 18 February 2023).

150. Shaw J, Gray CS, Baker GR, Denis JL, Breton M, Gutberg J, *et al.* Mechanisms, contexts and points of contention: operationalizing realist-informed research for complex health interventions. *BMC Med Res Methodol* 2018;**18**:178.

151. Hawe P, Shiell A, Riley T. Theorising interventions as events in systems. *Am J Community Psychol* 2009;**43**:267–76.

152. May CR, Johnson M, Finch T. Implementation, context and complexity. *Implement Sci* 2016;**11**:141.

153. Jones L, Hameiri S. COVID-19 and the failure of the neoliberal regulatory state. *Rev Int Polit Econ* 2021;**29**:1027–52.

154. Eccles MP, Foy R, Sales A, Wensing M, Mittman B. Implementation Science six years on--our evolving scope and common reasons for rejection without review. *Implement Sci* 2012;**7**:71.

155. May C. A rational model for assessing and evaluating complex interventions in health care. *BMC Health Serv Res* 2006;**6**:86.

156. May C, Finch T. Implementing, embedding, and integrating practices: an outline of normalization process theory. *Sociology* 2009;**43**:535–54.

157. May C. Towards a general theory of implementation. *Implement Sci* 2013;**8**:18.

158. McEvoy R, Ballini L, Maltoni S, ODonnell C, Mair F, MacFarlane A. A qualitative systematic review of studies using the normalization process theory to research implementation processes. *Implement Sci* 2014;**9**:2.

159. May CR, Cummings A, Girling M, Bracher M, Mair FS, May CM, *et al.* Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review. *Implement Sci* 2018;**13**:80.

160. Huddlestone L, Turner J, Eborall H, Hudson N, Davies M, Martin G. Application of normalisation process theory in understanding implementation processes in primary care settings in the UK: a systematic review. *BMC Fam Pract* 2020;**21**:1–16.

161. May C, Rapley T, Finch T. Normalization Process Theory. In Nilsen P, Birken S, editors. *International Handbook of Implementation Science*. London: Edward Elgar; 2020. pp. 144–67.

162. May C, Finch T, Mair F, Ballini L, Dowrick C, Eccles M, *et al.* Understanding the implementation of complex interventions in health care: the normalization process model. *BMC Health Serv Res* 2007;**7**:148.

163. May CR, Albers B, Bracher M, Finch TL, Gilbert A, Girling M, *et al.* Translational framework for implementation evaluation and research: a normalisation process theory coding manual for qualitative research and instrument development. *Implement Sci* 2022;**17**:19.

164. Finch TL, Rapley T, Girling M, Mair FS, Murray E, Treweek S, *et al.* Improving the normalization of complex interventions: measure development based on normalization process theory (NoMAD): study protocol. *Implement Sci* 2013; **8**:43. https://doi.org/10.1186/1748-5908-8-43

165. Horvath AO, Greenberg LS. Development and validation of the Working Alliance Inventory. *J Couns Psychol* 1989;**36**:223–33. https://doi.org/10.1037/0022-0167.36.2.223

166. Glaser BG. The constant comparative method of qualitative analysis. *Soc Probl* 1965;**12**:436–45.

167. Miller WR, Rollnick S. *Motivational Interviewing: Helping People Change.* 3rd edn. New York: Guilford Press; 2012.

Appendix 1 Patient and public involvement outputs

Defining your audience

	What we want them to think	How we want them to feel
Service users	• Relevant • Clear • Transparent and open • Up-to-date • Warm • Engaging • Easy to navigate • Welcome • Calm	• Understood • Not alone • Included • Reassured • Safe • Respected • Hopeful

FIGURE 22 Example output of consultation to develop the website.

FIGURE 23 Example additions to the Treatment Choices Booklet following LEAP contributions to training.

FIGURE 24 Published PPI-led EYE-2 blogs on the McPin website.

Four things I learnt running a social group for people with psychosis

Lived experience facilitator Gill shares why social groups offer more value than they've been given credit for, as well as some tips for setting up your own.

Gill Macafee

Are social groups the way forward to support people with psychosis?

Having facilitated such a group for 2 years, in my opinion, it is a definite yes.

As a lived experience facilitator, I found the whole experience an amazing journey of mind-provoking growth and I think the attendees benefitted greatly too.

Getting early support for psychosis

Around 7500 young people in England develop psychosis every year. Getting support from EIP services in the first 3 years can improve long-term outcomes, but at least a quarter of all young people drop out in the first 12 months.

I have slipped into psychosis on occasions over the past 25 years and became a volunteer Peer Mentor in 2018, following my last psychotic episode in 2016. Working in an inpatient environment, my work evolved into group work and I became interested in the dynamics of groups within the mental health sector.

For the past 2 years I have been working as the PPI lead on a research project called EYE-2 that aimed to develop ways to keep young people engaged.

One of the approaches we trialled was setting up social groups for young people. It was hoped that these groups would help the attendees to remain engaged in EIP services and consequently reduce the risk of a relapse.

'Without realizing it, each meet-up helps the members progress in their recovery and live a more positive life'.

Purpose and belonging

From my experience, social groups are wanted and needed by mental health service users.

They provide a social activity looked forward to by the attendees. They improve people's confidence, social interaction and self-awareness, while reducing social anxieties, social exclusion and fears about the outside world.

Without realising it, each meet-up helps the members progress in their recovery and live a more positive life, in the knowledge that they are not alone. The pace at which group members recover is made faster by other members being present and sharing experiences, along with solutions to shared problems they may have.

They have a great sense of belonging and purpose in life. For the one day a week that the group meets up they have routine, control and structure.

Top tips for facilitating social groups

As well as the power of social groups, I have learnt a lot about facilitating one. Here are four things that I think could help others thinking about doing something similar

Design the social groups around what the attendees want, not what is convenient for you

While the attendees enjoyed activities such as bowling, table tennis, walking, games of pool and darts, quizzes and trips to the cinema, the favourite pastime for group members was a pub meal. I think the reason for this was that their basic needs were fulfilled.

'Group members who weren't keen on doing the things agreed upon by the majority still showed up and were pleased with themselves for doing so'.

They had a chance to chat, share good and bad news, laugh together and simply socialise with people that they felt comfortable around. Also, they were enjoying a hearty meal while in good company.

Although this was their favourite pastime, I liked to vary things and thought it healthier to help them feel comfortable in other surroundings, such as at a bowling alley. During each session we would discuss the following week's options of things to do and would go with whatever was favoured by the majority.

I found that group members who weren't keen on doing the things agreed upon by the majority still showed up and were pleased with themselves for doing so. Every 3 weeks or so we would unanimously return to the pub for a meal.

Face to face is good but virtual also works

We had been running the social groups for 8 months when COVID hit. During this period it was possible to maintain a connection with the group members via Microsoft Teams. There was a group chat weekly, where everyone literally just caught up with each other, talked about everyday life and saw how we were each coping through these difficult times.

We also did activities that are easy to do online, such as quizzes. Everyone agreed that they didn't want visual contact, with two people saying that they felt uncomfortable seeing themselves on screen. This meant that the only technological equipment needed was a mobile phone.

Each of the four group members joined weekly throughout the 14 months of the pandemic, talking among themselves for at least an hour, sometimes longer. Although I was the host, I felt it important to take a back seat and allow them to talk to each other. I had maintained verbal contact with them separate to the group chat so encouraged and welcomed communication between themselves.

The fact that these groups continued during such testing times is testament that social groups do work.

In May 2021 F2F contact resumed and we went for a pub meal. The group members welcomed the return of weekly F2F sessions and we welcomed four new members. The group increased to eight attendees and remained so until the end of the study on 31 July 2021.

'I think that a key factor to the success of these groups was my lived experience'.

The importance of the group facilitator having lived experience

I think that a key factor to the success of these groups was my lived experience. This created relationships within the group which were valued for their reciprocity and enabled a build-up of mutual understanding.

My own lived experience helped me to support the group attendees with struggles that I had overcome and gave everyone hope with their own recovery. Also, I was able to talk with them about certain things relating to shared experiences.

This lived experience aspect helped to create a bond between the group. I felt at ease sharing my lived experience but only shared things when it seemed appropriate to do so. For example, I share my experience in the hope that it inspires others to recover, while knowing that the pace of this recovery is unique to the individual. We are each the same but different.

They were also able to identify with each other on certain things that they maybe didn't identify with me on and it was very much a group of unity based on mutual understanding and respect.

This created such a strong bond that the members would do additional social activities outside of the organised weekly session. They grew and blossomed as a group, as individuals and as friends, and helped each other along their recovery journeys.

As the EYE-2 study was coming to an end, it was particularly exciting to see one of the attendees take it upon himself to arrange for everyone to meet up for lunch without a facilitator present.

This was the ultimate goal of the study – that one member would gain enough confidence to arrange such a thing and the group would continue beyond the study. The group was finally theirs and in their total control.

Consider the size of the group

The smaller the group, the more personal it is. It was important for me to individualise the session for each member at some point during the weekly meet-up, for example, remembering that a member had a hospital appointment during the previous week and asking about how it went.

It is harder to remember such things when the group is larger. Also, some members are socially anxious and this can increase in a large group.

'The work put in to set up a group will be worth it as the rewards can be great'.

More valuable than they're given credit for

The experience of EYE-2 shows that social groups are more valuable than they have sometimes been given credit for. I think that once referrals are made, a facilitator should be able to use their lived experience and their peer skills to create a group of unity, understanding and mutuality.

They can form a socially comfortable environment where everyone feels valued, respected, heard and appreciated for their part in the group. The work put in to set up a group will be worth it as the rewards can be great, both for the attendees and the facilitator.

My journey from inpatient to peer mentor to group facilitator

Following a troubled young life, I had my first diagnosed psychotic episode in 1995. Many hospital admissions followed.

Things changed in 2016 when an inpatient stay was followed by 30 sessions of beneficial and insightful CBT. Already having insight into psychosis through my lived experience, I gained a lot of knowledge about myself and particularly my thought process. My paranoia became less intense and I am now able to rationalise.

It was around this time that I became a volunteer Peer Mentor in an inpatient environment focusing on arts and crafts. What I had expected to be peer work on a one-to-one basis evolved into group work and I found myself spending 3 hours twice a week with at least six service users at the same time. I realised that they were creating a bond not just with me, but with each other. These groups gave the attendees structure in an otherwise mundane existence.

I was then fortunate to be given the opportunity of setting up and facilitating the social groups on the EYE-2 study. I feel a great sense of satisfaction from the trial and the social groups.

The greatest satisfaction was seeing group members progressing on their recovery journey and particularly learning to do so without further encouragement from a facilitator. They got inspiration from me initially but went on to get it from and give it to each other.

How lived experience can help revamp mental health tools

Even well-established tools can benefit from service user input found Public Involvement Lead Carolyn Asher following a recent study

Carolyn Asher

There are lots of good reasons to involve service users in shaping mental health measurement tools.

Including service users in the redesign of mental health measures is an important move, because those with poor mental health are the ones who are tested by these psychological measures; because clinicians and academics do not have all the answers; because it's morally right to involve people who are the recipients of these measures; and because they have a unique perspective.

That said, unfortunately service user involvement does not always happen, which is why the EYE-2 study I've recently been involved with as a Public Involvement Lead is worth a closer look.

It rejected this tendency to leave out people who use services in the creation or adaptation of a psychological measure, developing a more person-centred and sensitive tool that could be used by clinicians and RAs.

Supporting people experiencing psychosis

The EYE-2 project is about improving services for people who have a first episode of psychosis, so that more people stay with the service and benefit from its support.

The project builds on the work of the first EYE project with Sussex Partnership Foundation Trust, and in Kent and Surrey, which developed a new approach with young people, their parents and EIP staff.

The project ran across five site locations – London, Manchester, Hampshire, Thames Valley and Cambridge-Norfolk. Participants in the study (people aged 18–35 under EIP services) completed regular questionnaires about their mental health, usually with the support of their care co-ordinator.

The HoNoS was used at several points in the intervention to measure how people were doing. Below is an example of one of the topics covered by HoNoS.

***Problems with relationships**: Rate most severe problem associated with active or passive withdrawal from social relationships and/or non-supportive, destructive or self-damaging relationships:*

- *0 No significant problems during the period;*
- *1 Minor non-clinical problem;*
- *2 Definite problems in making or sustaining supportive relationships; evident to others;*
- *3 Persisting major problems due to active or passive withdrawal form social relationships, and/or relationships that provide little or no comfort or support;*
- *4 Severe and distressing social isolation and/or withdrawal from social relationships.*

(Sourced from Assessments.pdf (peardonvillehouse.ca)*)*

'The whole structure of the HoNoS, as it stood, was not person-centred, or appropriate for telephone interviews'.

A need for standardised conversations

As you can see from the example, it relies on the doctor – or, in this case, the RA – making decisions based on their conversation with the person. This conversation is not standardised and can change each time it is done. One doctor may ask one thing to be able to score the HoNoS effectively while others may ask different things.

As each individual section is scored, a total for the individual is tallied. This can then be compared with previous scores or analysed, with a high score indicating a higher need for support.

The scale is very subjective with the final score based on the doctor's opinion, so it was felt it would be very hard for the EYE-2 RAs to complete.

The RAs wouldn't know the participants that well, if at all, especially if the participants had disengaged from the service and therefore the study. There were also concerns there would be no consistency between the study sites.

I think the whole structure of the HoNOS, as it stood, was not person-centred, or appropriate for telephone interviews, and required changes. This was echoed by those whose opinions we sought as part of the study.

Developing a fair system

To change it, we gathered input from carers and service users of the EIP services in the form of LEAPs, and held meetings to gather questions that could be asked by the RAs over the phone.

The service users and carers helped create these and came up with different wording that would help the RAs judge how to score that factor.

This was still subjective, but the questions were now aimed at providing a more structured approach to finding out the information, so that all sites were using the same questions.

Working in this way we ensured that we heard the voices of those impacted by Early Intervention services, and those receiving the EYE-2 intervention, as often as we could and that they had a participatory and creative role in this co-produced piece of work.

'It seemed to flow and didn't have any of the challenging wording that was on some of the previously revised versions'.

Revamping the Health of the Nation Outcome Scales

Six months later, the LEAPs met again to discuss the newly created – and much more in-depth – HoNOS questionnaire based on combining everyone's suggestions. The LEAPs then reviewed this questionnaire to come up with a more useable structure and conversational style.

This included altering the wording and order the questions were presented in, as it was felt the original HoNoS started with a topic that could cause issues when asked, such as talking about 'overactive', 'aggressive', 'disruptive' or 'agitated' behaviours.

After the second round of LEAP input, the questionnaire was revamped again by the study team. This version was then put to the Public Involvement Leads, who all also have lived experience. This resulted in a final version which was used by the RAs in the study.

They reported that it was easier to use than the original version. All LEAP participants were thanked for their involvement in the study and kept informed as to what had happened with their input.

Before the RAs used this new version of the HoNOS, they completed practice interviews with the Public Involvement Leads over the phone, including myself.

We assumed characters, though often ones based on real-life incidences from mine and others' lives, giving them confidence and practice at completing the HoNOS, as well as the chance to thoroughly test the revised version.

I found that it seemed to flow and didn't have any of the challenging wording that was on some of the previously revised versions. This shows that the public involvement was important, necessary and effective.

'Every researcher should be looking at involving the public throughout their study in a way that coproduces the materials, methods and data collection'.

So what happens next?

As the study's grant funding did not include a review of the HoNOS effectiveness and the study is now coming to an end, it might be useful for future work to more thoroughly explore how effective and well-received the new tool was.

As a Service User RA and Public Involvement Co-ordinator, I come across far too many studies that either haven't involved the public enough to make a sustainable difference or circumvent the process by not doing it thoroughly enough.

Involvement of the public is morally right, and funders and research bodies should make it easier and more realistic to get the funding to do it properly.

Every researcher should be looking at involving the public throughout their study in a way that coproduces the materials, methods and data collection, as well as the writing up and the dissemination of the results.

You can take a look at the social club booklet here:

EYE-2 BookletDownload

Appendix 2 Implementation study topic guide

Work Package 1: Qualitative topic guide to explore implementation of EYE 2 in the Sussex EIP service: version 1 09/02/18

Demographic details of Participant

1. Initials .....

2. Participant Number .....

3. Participant Age .....

4. Gender (please tick):

Male	Female
Gender queer	Non-binary
Prefer not to say	Trans
Other (please specify):	

5. Ethnicity (please tick):

White — English/Welsh/Scottish/Northern Irish/British

White — Irish

White — Gypsy or Irish Traveller

Any other white background, please describe

White and Black Caribbean

White and Asian

Any other mixed/multiple ethnic background, please describe

Indian

Pakistani

Bangladeshi

Chinese

Any other Asian background, please describe

African

Caribbean

Any other Black/African/Caribbean background, please describe

Arab

Any other ethnic group, please

6. Discipline/Profession/Role

.....

7. EIP **Service**

.....

Outline topic guide

Preparation: This topic guide is a guide only to discussion. Questions in bold are those deemed especially important.

Plan: Individual interviews with 12–16 clinicians (purposively sampled to represent all clinical disciplines across the six teams in Sussex).

Introduction: The EYE in FEP study is a study that we ran in Sussex EIP services between 2011 and 2015. It focused on improving the engagement of young people in EIP services. EIP services here were involved in focus groups, and interviews to develop the intervention approach. It included a training day, resources and booklets.

Topic guide:

1. **Informational resources** – What do you know or remember about the original EYE project training, intervention approach and resources?
    a. What were the main engagement approaches proposed?
    b. Is there anything else you can remember?
    c. What were the main resources developed?
    d. Is there anything else you can remember?

2. Are you currently using anything from the original EYE project? If so, what? If not, have you used anything in the past, and if so, what and for how long?
    a. EYE resources?
    b. EYE approaches and idea?

3. **Material resources** – How does the availability of the resources (both actual resources like booklets and computers with Wi-Fi, as well as your time) affect whether you use the EYE approach or not?
4. **Workability and integration (institutional)** – How do the approaches and materials from the EYE project fit with the way that you feel you ought to be working, and perhaps with the ways that you feel your peers think you ought to be working?
    a. What gets in the way of using the approaches/materials?
    b. What is it that encourages you to use the approaches/materials? prompts = compatibility with standard EIP approach/caseload/etc.

5. **Social norms (institutional)** – How have the EYE approach and materials changed the way that you work? How have they changed how the team works? Have they changed any policies or procedures? Have they changed any unwritten rules about how you work?
6. **Social norms (institutional)** – How well do the EYE approach and materials fit with managing risk issues? Does this affect how you use them?
7. **Social norms (institutional)** – How easy is it to use the EYE approach/resources when there are other service demands and pressures? (caseloads?)
8. **Social norms (social network)**
    a. Who uses the approach and materials?
    b. What governs who uses the approaches and materials?
    c. Who works hardest at engaging young people in the service?

9. Social norms (social network) Thinking about your team
    a. How do the attitudes and behaviours of staff, service users or carers towards the EYE approach and resources influence whether they use it or not?
    b. Has anyone strongly influenced their views about using the EYE materials recently or in the past?

10. **Individual intentions** Thinking about your team
    a. How compatible are the EYE project approach/resources with the beliefs, attitudes and behaviours of your team?

11. **Shared intentions**
    a. How consistent are the EYE project approach/resources with the beliefs, attitudes, behaviours and priorities of the team/service as a whole?

12. **Workability**
    a. What does using the EYE approach and resources involve doing?
    b. How possible is it to use these approaches in clinical practice? (bearing in mind space/staff/caseload)
    c. Use of website
    d. Use of booklets – help-seeking, EIP, friend and family, treatment choices?
    e. Use of motivational approaches focused on needs/goals?
    f. Use of open, honest communication in the context of difficult issues? (hospital/medication)
    g. Offering treatment choices?
    h. Involvement of the participants' whole social network including key family and friends?
    i. Use of peer workers/running of social groups?
    j. Use of schools pack?

13. **Integration** – How does use of the EYE approach and resources fit with other demands on your time, and other things that you need to do when working with service users in EIP?

14. **Coherence**
    a. What has helped you to know how to use the EYE approach and resources?
    b. What else could be provided to help you to know how to use the EYE approaches/resources?

15. **Cognitive participation**
    a. What do you do that helps you to put the EYE project approaches/resources into practice?
    b. What do you do to help others to use the approaches and resources? Have you introduced any new staff to the approach and resources? What have you told them?

16. **Cognitive participation**
    a. Is there anything that you do that gets in the way of or stops you using the EYE approaches and resources?
    b. **Timing** – are there times when you wouldn't use the EYE approaches and resources?

17. **Collective action**
    a. What have you done to help you to become better able to use the EYE approaches and resources?
    b. Or to engage better with young people using the service?

18. **Reflexive monitoring**
    a. **How do you and those you work with, know whether the approaches and resources that you use that are part of the EYE project are helpful?**
    b. How do you learn from this and apply it when working with more young people and their families in the future?

19. Is there anything else that we should include in the training and manual for new staff delivering the EYE project to help ensure that staff can make the best use of this approach in the future?
20. Is there anything else you wanted to add that we haven't already covered?

Ending – thank the person for their time, explain again what will happen to their information, how it will be used and the value of this study. Ask the person whether they would like copies of the materials when completed and whether they would like to remain in touch and receive updates about the study. Provide a study leaflet for them to contact us if they need to at any future time.

Appendix 3 Additional ethnicity study figure and tables

Ethnicity study topic guide

Qualitative topic guide to explore adaptations to EYE 2 for ethnic minority service users: version 1 09/02/18

Demographic details of Participant

8. Initials ……..

9. Participant Number ……

10. Participant Age ……

11. Gender (please tick):

Male	Female
Gender queer	Non-binary
Prefer not to say	Trans
Other (please specify):	

12. Ethnicity (please tick):

White — English/Welsh/Scottish/Northern Irish/British

White — Irish

White — Gypsy or Irish Traveller

Any other white background, please describe

White and Black Caribbean

White and Asian

Any other mixed/multiple ethnic background, please describe

Indian

Pakistani

Bangladeshi

Chinese

Any other Asian background, please describe

African

Caribbean

Any other Black/African/Caribbean background, please describe

Arab

Any other ethnic group, please

13. Religion ……

14. Sexuality ……..

Outline topic guide – for researchers

Preparation: research staff will be trained in issues relevant to culturally aware and sensitive interview approaches, and will be provided with a checklist of how to and how not to engage with people from different ethnic minority populations, and key information about different religious and cultural considerations. They will also be reminded about individuality and the risks of inadvertent stereotyping.

Additional consideration will be given to the gender of the researcher and their own ethnic background.

Access to the resources and website will be provided for at least 2 weeks before the interview.

This topic guide is a guide only to discussion. Questions in bold are those deemed especially important.

Plan: Individual interviews with 18–24 service users from London, Southampton and Manchester**.** Purposive sampling of key minority groups in each site

We'd like to find out a little bit more about how your needs and perspectives, as someone from a minority background, are considered in your EIP service.

For each question ask about this individual's own experiences, but also about other people from their minority group.

1. *What are your first thoughts about the booklets and materials? How do they fit with your cultural or spiritual beliefs?*
   - What do you like about the materials?
   - What's appealing?
   - What can you relate to?
   - What don't you like?
   - What additional information should be included? Which topics/issues?
   - What additional sections, considerations, should we include?
   - What should be changed?
   - Is there anything about these that does/doesn't fit in with the culture you or your family is from?
   - Is there anything about these that does/doesn't fit in with your spiritual beliefs?

2. *To what extent are your views, as someone from a minority background, represented in the health/mental health service?*
   - In written health materials (booklets/websites etc.) in general?
   - What works well for you in the health/mental health/EIP service?
   - What helps you to feel happy/relaxed?
   - All questions from here onwards are to be focused explicitly with reference to the EYE project materials – so use regular prompts such as:
     - How does this influence what might be included in the EYE booklets and website?
     - How does this influence how EIP clinicians should work with you?

3. *Social/cultural context*

Can you tell me a bit about yourself? What kind of area you live in? Who do you spend your time with? What your family are like?

- *Is there anything about where you live, your friends or your family that is important to who you are?*
- *How do you think this affects the way you talk or interact with your EIP service?*
- *Which groups of people do you feel comfortable with? Where do you feel you belong?*
- *How do you think this affects the way you talk or interact with your EIP service?*
- *How do you think your family influences your relationship with mental health services?*
- *Are there any beliefs (about mental health) that are specific to your family or wider community?*
- *How does your ethnic background influence your relationship with mental health services?*
- *How have your experiences with mental health services in the past affected your willingness to use services now?*

Possible prompts:

- What do your family and friends know about your experiences?
- What and who influences your opinion of your mental health?
- What/who influences your opinion of the mental health service?
- How do your family/friends understand your experiences?
- Do they have the same opinions as you?
- How do the views of your family differ in different generations?
- How close do you feel to family?
- How independent do you feel from family?
- How much do you agree with family?

4. *Emotional impact*
   - *Have you ever felt embarrassed about having difficulties with your mental health?*
   - *How has that influenced your willingness to use mental health services?*
   - *Have you ever felt blamed for having difficulties with your mental health?*
   - *How has that influenced your willingness to use mental health services?*
   - *Have you ever felt discriminated against?*
   - *How has that influenced your willingness to use mental health services?*
   - *How much trust do you feel in your mental health service?*
   - *How has trust influenced your willingness to use a mental health service?*

5. Spiritual issues
   - *Do you have any spiritual beliefs?*
   - *How do these fit with your understanding of your experiences?*
   - *How do these fit with using mental health services?*
   - *How do these fit with having treatment for your mental health?*
     - How might religious festivals or behaviours influence engagement, for example fasting/prayer/holy days etc.?

6. Practical issues
   - What practical issues affect whether you use mental health services?

Possible prompts

- immigration policies/status
- Role models/presence or absence of people who you identify with ethnically/culturally?
- Travel to appointments
- The gender of your key worker?
- Language/use of interpreters?

7. Technical Adjustments to aid engagement
   - *Would any changes to who you meet (ethnicity, sex, age, etc.) improve your relationship with your team?*
   - *Would any change in where you meet improve your relationship with your team?*
   - *What training/knowledge do staff need, in your opinion, about culture, ethnicity and spirituality?*
   - *What style of engagement do you prefer, for example collaborative, expert or something else?*

8. Consideration of concepts that might affect engagement:
   - *How do your beliefs about the best treatments (e.g. diet, acupuncture, traditional medicine) affect your engagement?*
   - *How do you think your physical body and mind are connected? Does this affect your engagement?*
   - *How much do you feel that your own goals and needs and the goals and needs of others are connected? Do your goals and needs affect your engagement?*
   - *Do you block out, avoid or find ways to cope with mental health, and does this affect your engagement?*

Ending – thank the person for their time, explain again what will happen to their information, how it will be used and the value of this study. Ask the person whether they would like copies of the materials when completed and whether they would like to remain in touch and receive updates about the study. Provide a study leaflet for them to contact us if they need to at any future time.

FIGURE 25 Transparent approaches to key issues including stigma, spirituality and difference.

TABLE 30 Prevalence of themes of the CAF applied to EYE-2, across ethnic subgroups

	Ethnicity								
Themes	Black British (*n* = 5)	White and Black (*n* = 6)	Black African (*n* = 3)	Black Caribbean (*n* = 1)	White and Asian (*n* = 1)	British Asian (*n* = 2)	White (*n* = 1)	Polish (*n* = 1)	Asian Bengali (*n* = 1)
Differing cognitions and beliefs	+++++	+++++	++	+	+	++	+	+	+
Multiple facets of culture	+++++	++++++	++	+	+	++	+	+	+
Language as a barrier to engagement		++		+		+	+	+	+
Stigma and discrimination	++++	+++++	++	+	+	+	+	+	+
Adaptations to EYE-2 resources	+++++	++++++	++	+	+	++	+	+	+
Trust in therapeutic alliance	+++++	++++++	++	+	+	++	+	+	+
Individual differences in therapeutic preferences	+	++	+		+	++	+	+	

Note
Each '+' indicates a participant transcript which features this theme.

TABLE 31 Cultural adaptation Framework (adapted from Rathod *et al.*, 2019) applied to EYE-2

Framework level	EYE-2 theme	Focus of EYE-2 adaptation arising from interviews	Suggestions for changes to EYE-2 approaches and resources arising from interviews
Philosophical orientation (e.g. Beliefs and attributions about illness, health and health providers; Help seeking behaviours defining pathways into care; cultural orientation towards psychotherapy; Level of acculturation/ cultural identity confusion.)	1. Differing cognitions and beliefs	1. Difficulties deciphering differences between religious experiences and psychosis experiences. 2. Conflicting perspectives between religious groups and NHS professionals.	*Awareness raising and training* 1. Train staff in order to raise awareness of differing beliefs and how to approach/discuss/ support these. 2. Emphasise that what works for one individual may not work for another. 3. Include a section on considering different cultures and ethnicities. *Additions/changes to booklets/resources.* 4. Include sections on differing beliefs and difference from own beliefs. 5. Ensure terminology in resources is acceptable to patient and family. 6. Clarify how services might approach religion and spirituality in treatment.
	2. Multiple facets of culture	1. Oscillation between host culture, culture of origin and societal culture. Culture as a mix of where you're from, where you live and your own values. Leading to difficulty balancing between different cultures for example parents and own culture, for example mum is white and dad is Chinese. Family conflict can affect involvement with services, for example lack of understanding or different views on MH and treatment. 2. Multiple definitions of culture – Some people described identifying with multiple minority groups, which could lead to more difficulties, but also described identifying more with one group than others (e.g. LGBTQ) leading to a sense of belonging and independence, and freedom of expression. 3. Some minority groups are more likely to experience mental health problems but lack of representation in booklets may mean they have nothing to relate to or feel that they do not matter (e.g. LGBTQ individuals). Booklets don't discuss cultures or different ethnicities. 4. Spirituality – Need to understand spiritual beliefs of individuals and their families/cultures and the impact on mental health, help-seeking and engagement (e.g. use of spiritual healers/ meditation).	*Awareness raising and training* 1. Consider undertaking prior background research and demographic profiling of cultures on caseload. 2. Enhance understanding of the backgrounds behind different cultures, including community, strengths, beliefs, attributions and treatment views. Staff need training on religion, sexuality and spirituality. This will encourage them to open up conversations, allowing young people to relate. Showing that interest and awareness will increase trust and engagement. 3. Consider patient's story, cultural identity; acculturation level and acculturation stress especially where second generation is involved. 4. Recommend Guidelines for staff on how to support individuals from mixed background/ family to understand their identity. 5. Ensure staff are aware when discussing and sharing information with families that an individual may not agree with the religious/ spiritual views of their family. 6. Involve diverse range of experts by experience in staff training. 7. Include information about alternative help-seeking behaviours in different cultures in staff training. 8. Ensure the training is meaningful and not just a tickbox. 9. To be aware that in sexuality, definitions can be confusing or difficult to understand, define and come to terms with.

continued

TABLE 31 Cultural adaptation Framework (adapted from Rathod *et al.*, 2019) applied to EYE-2 (*continued*)

Framework level	EYE-2 theme	Focus of EYE-2 adaptation arising from interviews	Suggestions for changes to EYE-2 approaches and resources arising from interviews
		5. Religion – Need to understand that there are many subgroups within a religion, and that people who identify with the same religion may have differing views on their faith, even within the same family. 6. Sexuality – Need to understand there are different subcultures within LGBTQ, for example transsexual, bisexual, pansexual. 7. Spiritual and religious influences can be helpful (e.g. prayer/reading spiritual text for coping, sharing spiritual behaviours with friends/support group), supporting engagement, as well as having physical impacts (e.g. fasting), and being linked to unusual religious beliefs. 8. Sexuality can provide positive support, for example feeling safer and less judged, being part of cultural/community and events, for example Pride, Gay Village, but can also lead to discrimination, anxiety coming out, and struggle with non-acceptance from family that can add to their MH difficulties.	*Additions/changes to booklets/resources* 1. Include information in EYE-2 booklets and website about cultural identity, and about spiritual beliefs and how they might affect help-seeking, engagement with services and treatments. 2. include sections on the website for different religions. 3. Develop a family booklet that considers different non-Western cultures and views of mental health. 4. Ensure images in booklets are inclusive of different religions and ethnicities. 5. Include more pictures, colour and artwork in booklets/website representing a variety of ages/cultures/values (e.g. work, families, etc.).
Practical considerations and social factors (e.g. racial discrimination and effects)	3. Stigma and discrimination	1. Family struggle to talk about mental health or do not speak about it at all. People don't want to review resources with family. around, fear being judged, and fear of family reputation 2. Stigma more common in someone's home country.	*Awareness raising and training* 1. Consider staff training on mental health stigma in different cultures. 2. Provide staff training/guidance on immigration and impact on service engagement. 3. Staff awareness/guidance on the stigma of mental health within families.
		3. Caution/worry about sexuality outside LGBTQ community, fear that staff will discriminate and judge. 4. Stigma of sexuality in some religions causes mental ill-health. 5. Young people may find it difficult to attend appointments due to not being allowed to travel alone and parent being unable to take them.	*Additions/changes to booklets and resources* 4. Ensure booklets discuss how to disclose/discuss mental health problems 5. Include a 'quick close' option on the website to come off it 6. Consider including information on sexuality in family booklets to raise that awareness/break barriers.
Theoretical modifications of concepts	4. Individual differences in therapeutic preferences	1. Individuals may understand and perceive the world in very different ways. Everyone's experiences are different. Needs constantly changing, depends on the stage an individual is at. 2. Some participants prefer a more directive approach than the collaborative approach preferred in West.	*Awareness raising and training* 1. Improve staff awareness of individual differences.
Technical adjustments (e.g. setting/environment; language/interpreters; therapeutic relationship/style; family structure and goals; role of religion)	5. Trust in therapeutic alliance	1. Difficulties of first engagement, police being involved and feeling their free will was taken, impacted on trust. 2. Preference for care co-ordinator could be asked (i.e. gender, ethnicity, personality, etc.). 3. Religion/spirituality/sexuality is never discussed but may be linked to someone's difficulties.	*Approaches to increase trust* 1. Involve service users in peer support, staff training. 2. Enable options to be treated by staff from a similar background. 3. Improve staff understanding, engagement and handling and approaching confidential information to build trust especially when discussing with family.

TABLE 31 Cultural adaptation Framework (adapted from Rathod *et al.*, 2019) applied to EYE-2 (*continued*)

Framework level	EYE-2 theme	Focus of EYE-2 adaptation arising from interviews	Suggestions for changes to EYE-2 approaches and resources arising from interviews
	6. Language as a barrier to engagement	1. Communication is key to help break down barriers and judgements, but people with a language barrier may struggle to access help and resources. 2. Use of interpreters can compromise confidentiality.	*Awareness raising and training* 1. Raise awareness with staff about the confidentiality concerns relating to the use of interpreters. *Additions/changes to booklets and resources* 2. Ensure website and stories are available in a variety of mediums (e.g. written, audio, visual). 3. Provide audio options of segments on the website in other languages. 4. Providing family members and individuals with booklets/resources in their own language at the beginning of their journey.
	7. Adaptations to EYE-2 approaches and resources	1. Young people need something they can relate to. 2. No demographic information or awareness of any minority group in the booklets, or any information on religion, although difficult to cover all religions.	All suggestions for awareness raising, training approaches, and additions/changes are listed above.

Appendix 4 Additional tables from *Chapter 5* effectiveness

TABLE 32 Completeness of QPR and DIALOG data

	Completeness for sEIP only					Completeness forEYE-2 + sEIP					Completeness for overall				
	n 100%	*n* ≥ 80%	*n* 1–79%	*n* 0%	Total	*n* 100%	*n* ≥ 80%	*n* 1–79%	*n* 0%	Total	*n* 100%	*n* ≥ 80%	*n* 1–79%	*n* 0%	Total
QPR															
Baseline	237	19	2	117	375	352	15	1	284	652	589	34	3	401	1027
Month 6	192	7	1	175	375	234	22	0	396	652	426	29	1	571	1027
Month 12	146	3	0	226	375	218	7	1	426	652	364	10	1	652	1027
DIALOG QoL															
Baseline	241	22	2	110	375	358	17	8	269	652	599	39	10	379	1027
Month 6	188	11	2	174	375	244	13	6	389	652	432	24	8	563	1027
Month 12	145	6	0	224	375	216	9	4	423	652	361	15	4	647	1027
DIALOG TS															
Baseline	244	N/A	18	113	375	351	N/A	28	273	652	595	N/A	46	386	1027
Month 6	192	N/A	9	174	375	252	N/A	11	389	652	444	N/A	20	563	1027
Month 12	144	N/A	7	224	375	215	N/A	13	424	652	359	N/A	20	648	1027

TABLE 33 Health of the Nation Outcome Scales, QPR and DIALOG data collection within/outside of collections windows at baseline, m6 and m12, by intervention arm

	sEIP only		EYE-2 + sEIP		Overall	
	n	%	*n*	%	*n*	%
HoNOS collection at bl						
In window	313	84.4	551	86.1	864	85.5
Out of window	58	15.6	89	13.9	147	14.5
Total	371	100.0	640	100.0	1011	100.0
HoNOS collection at m6						
In window	189	59.6	331	61.6	520	60.9
Out of window	128	40.4	206	38.4	334	39.1
Total	317	100.0	537	100.0	854	100.0
HoNOS collection at m12						
In window	161	63.9	232	55.4	393	58.6
Out of window	91	36.1	187	44.6	278	41.4
Total	252	100.0	419	100.0	671	100.0
QPR collection at bl						
In window	125	48.8	157	42.9	282	45.3
Out of window	131	51.2	209	57.1	340	54.7
Total	256	100.0	366	100.0	622	100.0
QPR collection at m6						
In window	103	51.8	106	41.4	209	45.9
Out of window	96	48.2	150	58.6	246	54.1
Total	199	100.0	256	100.0	455	100.0
QPR collection at m12						
In window	84	56.4	124	55.1	208	55.6
Out of window	65	43.6	101	44.9	166	44.4
Total	149	100.0	225	100.0	374	100.0
DIALOG collection at bl						
In window	123	51.0	154	43.1	277	46.3
Out of window	118	49.0	203	56.9	321	53.7
Total	241	100.0	357	100.0	598	100.0
DIALOG collection at m6						
In window	101	53.7	100	41.0	201	46.5
Out of window	87	46.3	144	59.0	231	53.5
Total	188	100.0	244	100.0	432	100.0
DIALOG collection at m12						
In window	83	57.2	119	55.1	202	56.0
Out of window	62	42.8	97	44.9	159	44.0
Total	145	100.0	216	100.0	361	100.0

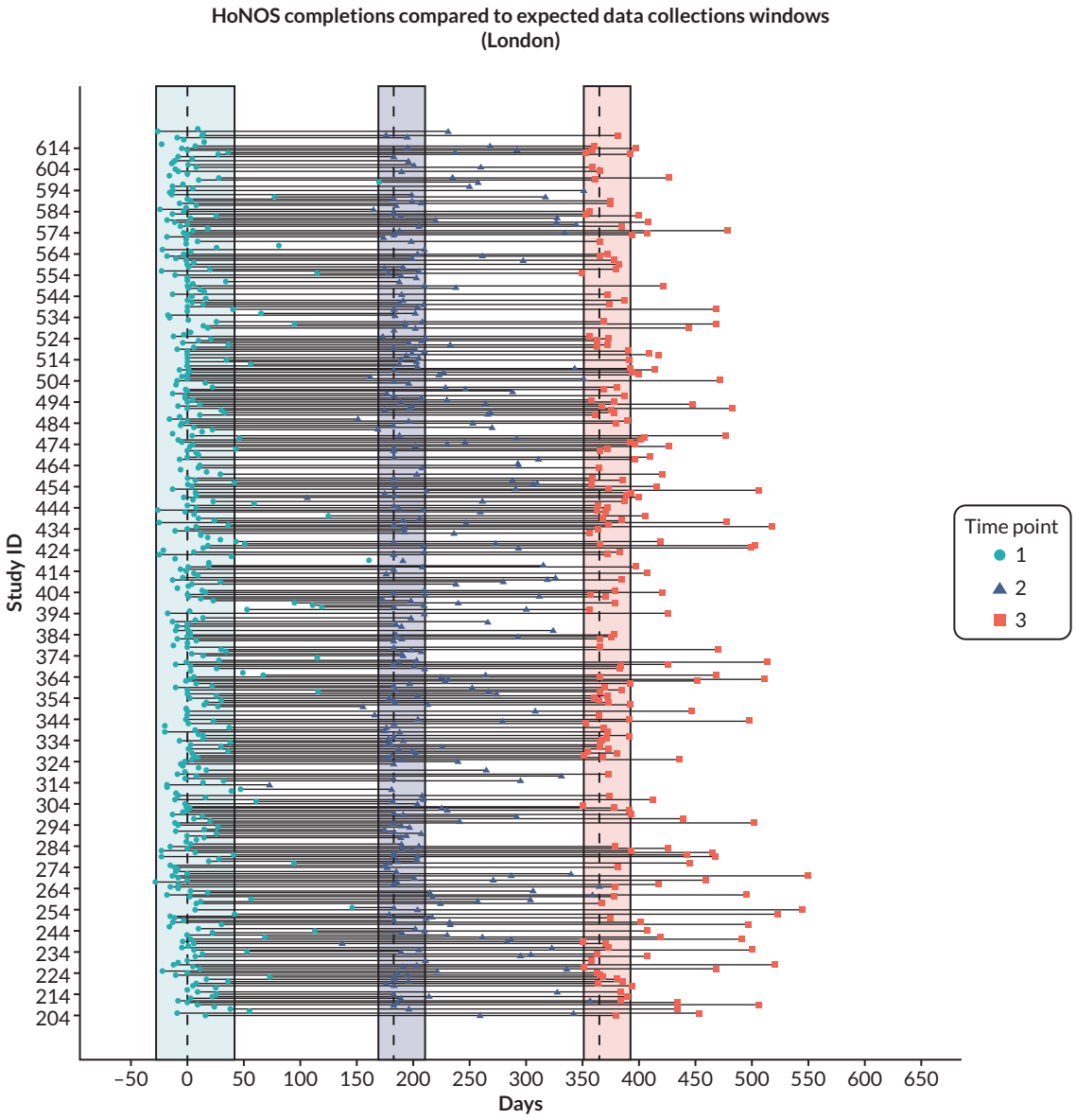

FIGURE 26 Health of the Nation Outcome Scales completions compared to time-point windows in London.

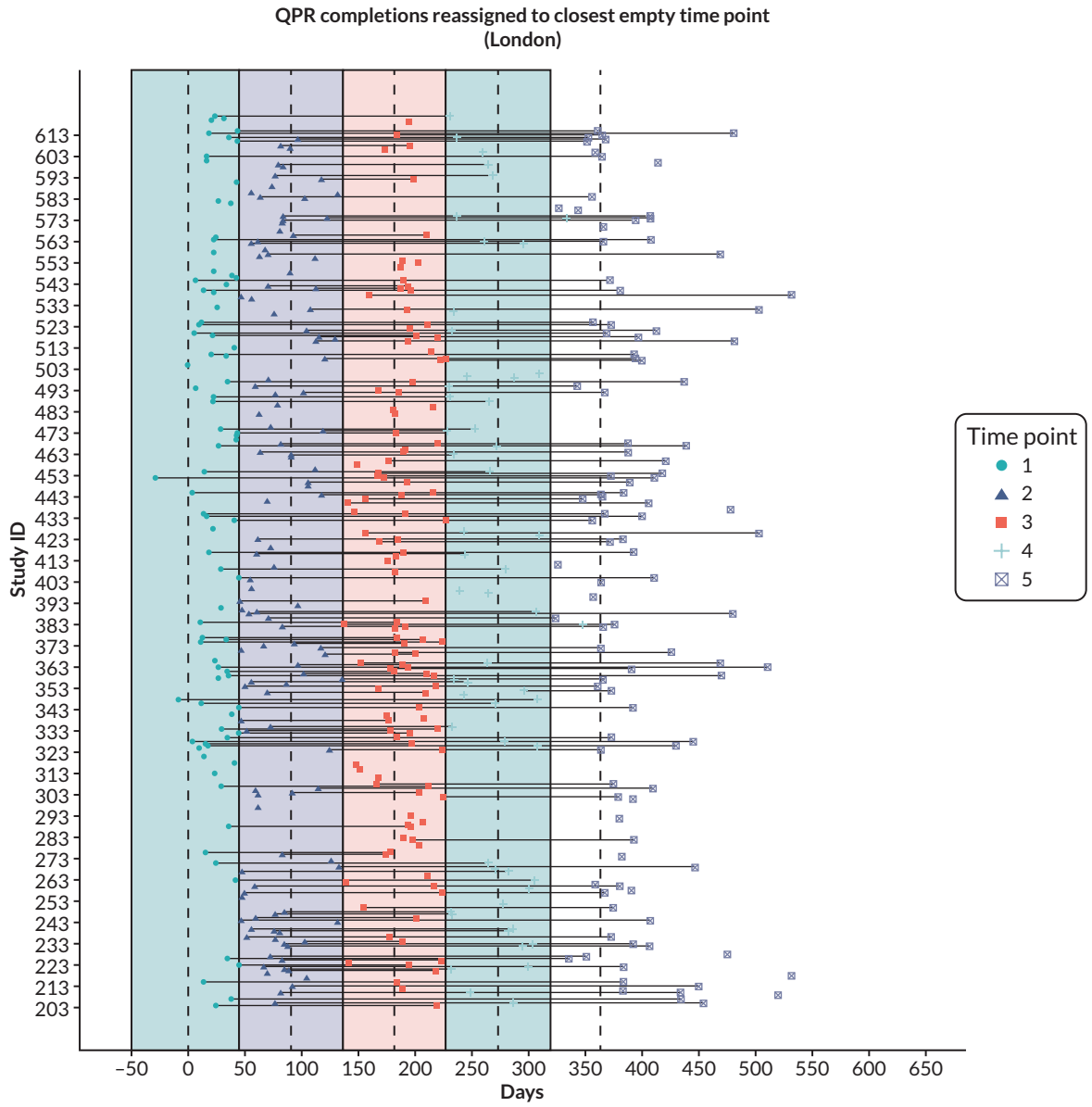

FIGURE 27 Questionnaire on the process of recovery completions reassigned to closest empty time-point windows in London.

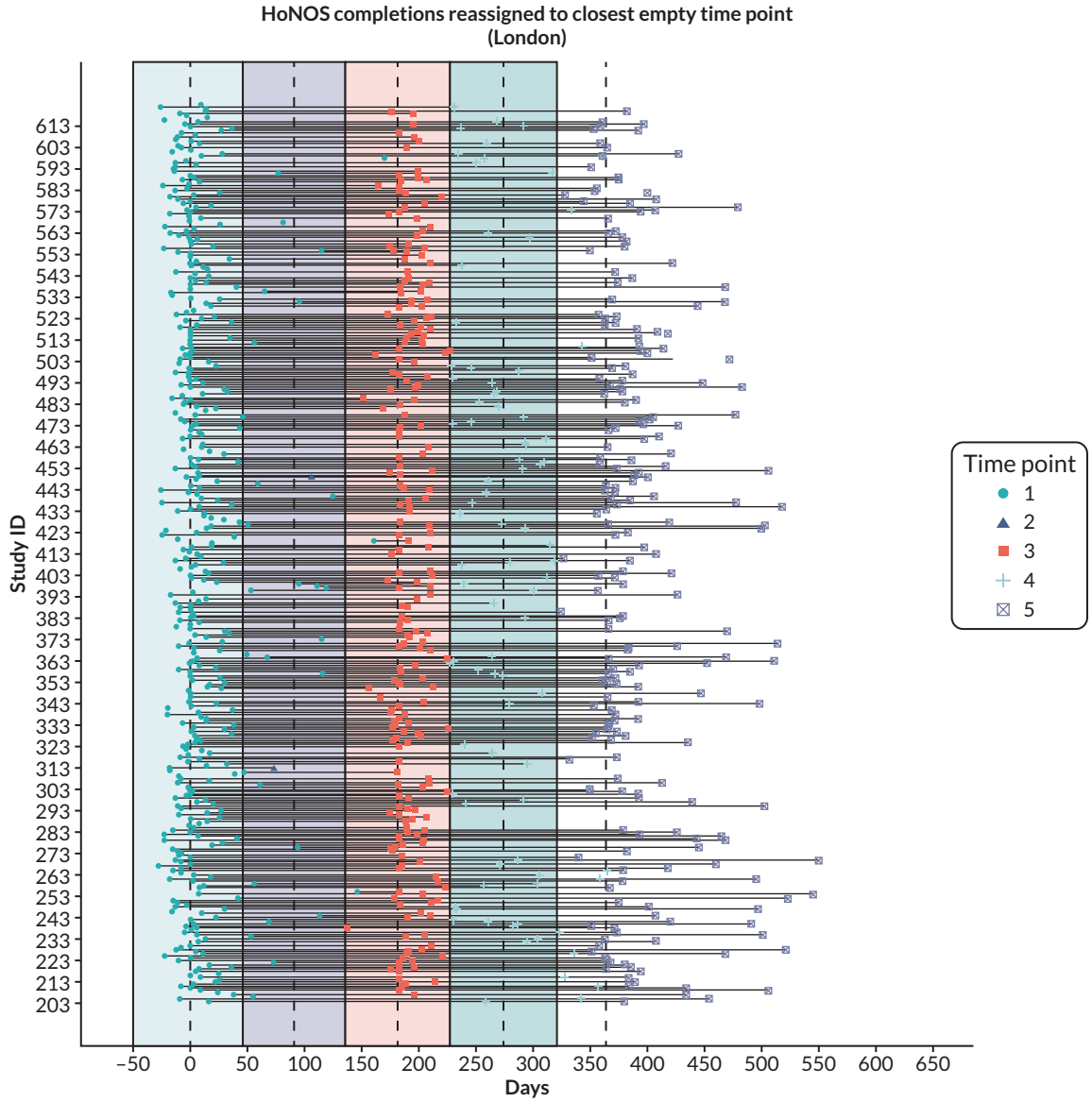

FIGURE 28 Health of the Nation Outcome Scales completions reassigned to closest empty time-point windows in London.

TABLE 34 Number of participants with data for HoNOS, QPR and DIALOG at each time point after reassignment, by intervention arm

	sEIP only	EYE-2 + sEIP	Overall
	n	*n*	*n*
HoNOS			
Baseline	349	582	931
Month 3	1	2	3
Month 6	193	315	508
Month 9	76	125	201
Month 12	235	400	635
QPR			
Baseline	138	173	311
Month 3	108	170	278
Month 6	138	169	307
Month 9	62	101	163
Month 12	158	235	393
DIALOG			
Baseline	133	169	302
Month 3	97	166	263
Month 6	131	163	294
Month 9	59	93	152
Month 12	154	227	381

Across the next four tables, the 'Analysis with data MAR assumption' row represents the model where participants with missing data have been excluded – equivalent to the assumption that variables related to missingness were included in the analysis. This is equivalent to the approach used in the main analysis models for HoNOS, QPR and DIALOG where participants missing all outcome data or any data for covariates were excluded. The other rows represent situations where missingness is MNAR – where missingness is related to the outcome score. Missing outcome data is replaced with an assumed mean response in the sEIP-only arm and with an assumed mean response in the EYE-2 + sEIP arm the same as in the sEIP-only arm and this value ± *d* (where *d* is 5 for HoNOS, 10 for QPR and 1 for DIALOG). The adjusted treatment effect is calculated under each of these conditions to see if the results (i.e. the arm favoured) change compared to the analysis assuming missing data is MAR.

TABLE 35 Missingness sensitivity analyses for HoNOS overall score

Assumed mean response for participants missing data		Effect of assumptions		
sEIP only	EYE-2 + sEIP	Adjusted treatment effect	95% CI	Favoured arm
5	0	−1.78	−2.90 to −0.67	sEIP only
5	5	0.08	−1.03 to 1.20	Neither
5	10	1.95	0.83 to 3.07	EYE-2 + sEIP
10	5	−1.85	−2.97 to −0.73	sEIP only
10	10	0.02	−1.10 to 1.13	Neither
10	15	1.88	0.77 to 3.00	EYE-2 + sEIP
15	10	−1.91	−3.03 to −0.80	sEIP only
15	15	−0.05	−1.16 to 1.07	Neither
15	20	1.82	0.70 to 2.94	EYE-2 + sEIP
20	15	−1.98	−3.10 to −0.86	sEIP only
20	20	−0.11	−1.23 to 1.00	Neither
20	25	1.75	0.64 to 2.87	EYE-2 + sEIP
25	20	−2.05	−3.16 to −0.93	sEIP only
25	25	−0.18	−1.30 to 0.94	Neither
25	30	1.69	0.57 to 2.80	EYE-2 + sEIP
30	25	−2.11	−3.23 to −1.00	sEIP only
30	30	−0.25	−1.36 to 0.87	Neither
30	35	1.62	0.50 to 2.74	EYE-2 + sEIP
35	30	−2.18	−3.29 to −1.06	sEIP only
35	35	−0.31	−1.43 to 0.81	Neither
35	40	1.56	0.44 to 2.67	EYE-2 + sEIP
40	35	−2.24	−3.36 to −1.13	sEIP only
40	40	−0.38	−1.49 to 0.74	Neither
40	45	1.49	0.37 to 2.61	EYE-2 + sEIP
43	38	−2.28	−3.40 to −1.17	sEIP only
43	43	−0.42	−1.53 to 0.70	Neither
43	48	1.45	0.33 to 2.57	EYE-2 + sEIP
Complete case analysis		0.06	−0.41 to 0.54	Neither

TABLE 36 Missingness sensitivity analyses for QPR score

Assumed mean response for participants missing data		Effect of assumptions		
sEIP only	EYE-2 + sEIP	Adjusted treatment effect	95% CI	Favoured arm
10	0	−6.42	−8.66 to −4.18	sEIP only
10	10	−0.63	−2.88 to 1.61	Neither
10	20	5.15	2.91 to 7.39	EYE-2 + sEIP
20	10	−7.03	−9.27 to -4.79	sEIP only
20	20	−1.24	−3.48 to 1.00	Neither
20	30	4.54	2.30 to 6.78	EYE-2 + sEIP
30	20	−7.64	−9.88 to −5.40	sEIP only
30	30	−1.85	−4.09 to 0.39	Neither
30	40	3.93	1.69 to 6.17	EYE-2 + sEIP
40	30	−8.25	−10.49 to −6.01	sEIP only
40	40	−2.46	−4.70 to −0.22	sEIP only
40	50	3.33	1.08 to 5.57	EYE-2 + sEIP
50	40	−8.86	−11.10 to −6.62	sEIP only
50	50	−3.07	−5.31 to −0.83	sEIP only
50	60	2.72	0.48 to 4.96	EYE-2 + sEIP
Complete case analysis		−0.03	−2.27 to 2.22	Neither

TABLE 37 Missingness sensitivity analyses for DIALOG QOL score

Assumed mean response for participants missing data		Effect of assumptions		
sEIP only	EYE-2 + sEIP	Adjusted treatment effect	95% CI	Favoured arm
2	1	−0.82	−1.02 to −0.63	sEIP only
2	2	−0.24	−0.43 to −0.04	sEIP only
2	3	0.35	0.16 to 0.55	EYE-2 + sEIP
3	2	−0.89	−1.08 to −0.69	sEIP only
3	3	−0.30	−0.49 to −0.10	sEIP only
3	4	0.29	0.10 to 0.49	EYE-2 + sEIP
4	3	−0.95	−1.14 to −0.76	sEIP only
4	4	−0.36	−0.55 to −0.17	sEIP only
4	5	0.23	0.04 to 0.42	EYE-2 + sEIP
5	4	−1.01	−1.21 to −0.82	sEIP only
5	5	−0.42	−0.62 to −0.23	sEIP only
5	6	0.17	−0.03 to 0.36	Neither
6	5	−1.07	−1.27 to −0.88	sEIP only
6	6	−0.49	−0.68 to −0.29	sEIP only
6	7	0.10	−0.09 to 0.30	Neither
Complete case analysis		−0.11	−0.30 to 0.08	Neither

TABLE 38 Missingness sensitivity analyses for DIALOG TS score

Assumed mean response for participants missing data		Effect of assumptions		
sEIP only	EYE-2 + sEIP	Adjusted treatment effect	95% CI	Favoured arm
2	1	−0.69	−0.89 to −0.49	sEIP only
2	2	−0.10	−0.30 to 0.10	None
2	3	0.49	0.29 to 0.70	EYE-2 + sEIP
3	2	−0.75	−0.95 to −0.55	sEIP only
3	3	−0.16	−0.36 to 0.04	None
3	4	0.43	0.23 to 0.64	EYE-2 + sEIP
4	3	−0.81	−1.01 to −0.61	sEIP only
4	4	−0.22	−0.42 to −0.02	sEIP only
4	5	0.38	0.17 to 0.58	EYE-2 + sEIP
5	4	−0.87	−1.07 to −0.67	sEIP only
5	5	−0.28	−0.48 to −0.08	sEIP only
5	6	0.32	0.11 to 0.52	EYE-2 + sEIP
6	5	−0.93	−1.13 to −0.73	sEIP only
6	6	−0.34	−0.54 to −0.14	sEIP only
6	7	0.26	0.05 to 0.46	EYE-2 + sEIP
Analysis with data MAR assumption		0.02	−0.18 to 0.22	None

Appendix 5 The training paper

Implementing and evaluating training programmes for Early Intervention in Psychosis staff in a cluster randomised controlled trial of the Early Youth Engagement in first episode psychosis (EYE-2) intervention – Manuscript prepared by Jenny Gu

Abstract

Early Intervention in Psychosis (EIP) services improve outcomes for young people with first-episode psychosis, but 25% disengage within the first 12 months, at significant cost to their health and well-being, society, and the NHS. Our pilot work with young service users, carers, and EIP clinicians shed light on the barriers and facilitators of Early Youth Engagement in first episode psychosis (EYE study) and informed the development of a team-based, motivational, Early Youth Engagement intervention (EYE-2) to improve engagement in EIP services. A cluster randomised controlled trial (RCT) is underway to test the effectiveness of the EYE-2 intervention compared to treatment as usual (TAU) in increasing time to disengagement and improving health and well-being outcomes. This RCT required workforce training in the EYE-2 intervention and robust collection of routine outcome data across all participating EIP services and this paper reports on the evaluation of these staff training programmes. Training was delivered to staff in 20 EIP services across 9 National Health Service Trusts and five broad regions in the United Kingdom. Staff from all services, randomised to both TAU and EYE-2 arms, received a half-day training on robust collection of routine outcome data. Staff from services randomised to the intervention arm received an additional one and a half days of training on the intervention approach. Evaluation of training programmes employed a pre–post self-report survey design. Three hundred and thirty-six staff (72.73% of total staff employed) across 20 EIP services attended training: 132 (69.47%) from teams randomised to TAU received training in robust data collection and 204 (75%) from teams randomised to the intervention received training in both robust data collection and the EYE-2 intervention. Findings showed that the training programmes were well-accepted and resulted in improvements in staff competence in engaging young people with psychosis and collecting routine outcome data to continually assess their progress. Thematic analysis of qualitative feedback identified four overarching themes of helpful and unhelpful aspects of both training programmes relating to: (1) Preferred approaches to training, (2) Enhanced personal knowledge, (3) Application to and impact on clinical practice and (4) Usefulness of the resources. Current findings contribute to the limited research on EIP workforce training and have the potential to inform future training initiatives.

Introduction

In England, 1–2% of the population (McManus *et al.*, 2016; Sartorius *et al.*, 1986), 7500 new young people each year (Department of Health, 2000), develop psychosis. Psychosis has devastating consequences, including substantially poorer QoL and high disability-adjusted life-year losses (Rossler *et al.*, 2005). The financial cost of psychosis to society, including health care, families, unemployment and death, is estimated at £11.8 billion per year (The Schizophrenia Commission, 2012). People with psychosis die up to 25 years earlier than the general population (Parks *et al.*, 2006), one-third from suicide, usually within the first 3–5 years (Bertelsen *et al.*, 2007; Wiersma *et al.*, 1998). The first 2–3 years are pivotal in determining long-term trajectories (Birchwood and Fiorillo, 2000; Birchwood *et al.*, 1998; Bottlender *et al.*, 2003; Harris *et al.*, 2005; Mihalopoulos *et al.*, 2009; Pelosi and Birchwood, 2003).

Early Intervention in Psychosis services are proactive, person-centred mental health services offering early detection and treatment in the critical 3-year period (e.g. Department of Health, 2009; Harris *et al.*, 2008; Marshall *et al.*, 2005; Melle *et al.*, 2006; World Health Organization and International Early Psychosis Association, 2004). EIP services demonstrate savings of 30–50% over standard care, over periods of at least 8 years (McCrone *et al.*, 2010; McCrone and Knapp, 2007). There is sustained interest and intent to increase access to EIP services for people of all ages who develop a first episode of psychosis. The recent AWTS [NHS England, the National Collaborating Centre for Mental Health, and the National Institute for Health and Care Excellence (NICE), 2016] requires all CCGs to ensure that from 2016, at least 50% of all new emerging psychosis cases in England are engaged within 2 weeks

with a NICE-concordant EIP service. EIP service access is 'a clear national priority for the NHS' and local NHS services must include EIP development in their immediate and long-term sustainability and transformation plans (NHS England, the National Collaborating Centre for Mental Health, and NICE, 2016). This has been supported by £70 million for training and staff by 2020 (NHS England, 2016).

Despite national policy, substantial investment, and service structure to ensure that young people are proactively engaged in assessment, and offered a full EIP care package, disengagement from services is high: estimated at 30% of young people in a systematic review across all service types and follow-up periods (Doyle *et al.*, 2014), and 25% within the first 12 months in standalone EIP services (Conus *et al.*, 2010; Turner *et al.*, 2007). This is a major problem. Engagement with EIP services leads to increased service user satisfaction, fewer symptoms, fewer relapses and hospital admissions, better health and well-being, improved social and occupational function, and fewer suicides (e.g. Dodgson *et al.*, 2008; Garety *et al.*, 2006; Harris *et al.*, 2005; Nordentoft *et al.*, 2002) in the medium to long term (e.g. Melle *et al.*, 2006; Nordentoft *et al.*, 2002; Renju and Birchwood, 2005). Disengagement of young people with psychosis represents a significant cost to their health and well-being and impacts on families, society, and the NHS. There is therefore an expressed need from researchers and NHS management to focus on engagement, with some researchers suggesting that this is the most important outcome of EIP services (Tait *et al.*, 2003). The College Centre for Quality Improvement has made time to disengage a recent EIP audit requirement (Royal College of Psychiatrists, 2016).

Our pilot work has shed light on the barriers and facilitators of Early Youth Engagement in first-episode psychosis (EYE study) and provides evidence for methods to promote engagement (e.g. Greenwood *et al.*, in press). Findings from the EYE study have informed the development of a team-based, motivational, Early Youth Engagement intervention (EYE-2) to improve engagement in EIP services. We are in the process of conducting a multisite cluster RCT testing the effectiveness of the EYE-2 intervention in addition to usual practice in EIP services compared to treatment as usual (TAU) in increasing time to disengagement (primary outcome) and improving mental health, social and occupational functioning, recovery, and QoL and service satisfaction (secondary outcomes) (Greenwood *et al.*, 2021). Secondary outcomes are NHS England-mandated routine outcomes collected by EIP staff. This RCT required workforce training in the EYE-2 intervention and robust collection of data from routine outcome measures across all participating EIP services; all staff in 20 EIP teams across 9 NHS Trusts and five regions of the United Kingdom. This paper reports on the evaluation of the intervention and data collection training programmes delivered to staff from participating EIP services prior to the start of the RCT.

The Early Youth Engagement-2 intervention

The EYE-2 intervention was developed based on pilot work which identified the barriers and facilitators to Early Youth Engagement (EYE study) with EIP services from the perspective of young psychosis service users, families and young people not currently using services, for example in schools, colleges and homeless hostels (e.g. Greenwood *et al.*, in press). This work identified core themes that could serve as a barrier or facilitator to engagement: (1) open, honest, communication; (2) consideration and involvement of the social network; (3) the service as a whole and the extent to which there was collaboration in relation to complex treatment choices such as medication and hospitalisation; (4) the clinical staff: their actions, attitude, and knowledge, and the extent to which they could support service users' own holistic life goals and (5) the service user's own personal experiences and preferences and the extent to which clinicians could promote and elicit trust and honesty across personal, family, and system boundaries. A subsequent consultation with EIP clinicians and managers translated these findings into a new youth-focused motivational engagement intervention (EYE-2 intervention).

The intervention, delivered by care co-ordinators and EIP teams and incorporated into standardised EIP services, is based on motivational interviewing techniques and open social communication and focuses on what and how we communicate with young people and their families. The intervention is supported by a staff training programme and training manuals, a website with moderated forum, a series of myth-busting booklets, and peer-led social groups. The focus of the intervention is to promote engagement with treatments, and the realisation of the young person's goals, through collaborative knowledge sharing in the context of a hopeful systemic therapeutic relationship between the young person, their care co-ordinator and team, and their family and broader social network. This approach builds on,

and is complementary to, the ethos of EIP services. While the EIP model outlines what to do, the EYE-2 intervention describes how to do it: providing clinicians with specific information and resources to enhance their engagement approaches with their service users.

Our pilot study testing the EYE-2 intervention trained over 80% of staff in six teams in Sussex and one in Kent in the intervention. This study found that service disengagement decreased from 24% pre-EYE-2 intervention to 14.5% post intervention. Qualitative feedback from service users and families revealed improvements in service user personal recovery (social inclusion, hope, trust, practical goals) and engagement (communication, collaboration, family involvement). Clinicians also reported more pride and professionalism in their service.

The current study

Successful implementation of interventions in the NHS is challenging, even for those that are directly in line with national policy. A key barrier to implementation is the quality of the training programme designed to deliver the intervention (e.g. Berry and Haddock, 2008; Shafran *et al.*, 2009). Before an intervention in EIP services can be implemented, it is important to demonstrate that training could be delivered to large numbers of EIP staff and it is well accepted and led to improvement in knowledge, confidence and skills to enable staff to effectively engage and support young psychosis service users, with a view to improving mental health and functional outcomes. Despite the evaluation of workforce training being a necessary prerequisite to the implementation of interventions, few studies have evaluated training programmes in mental health services and none have done this for EIP services.

The aim of the current study was to deliver and evaluate training programmes for EIP staff as part of the cluster RCT comparing the EYE-2 intervention to TAU (Greenwood *et al.*, 2021). Specific objectives were to: (1) deliver the training programmes to all staff in EIP services in 20 teams across 9 NHS Trusts and five regions of the United Kingdom, (2) record staff attendance at training sessions, (3) assess experiences of the training, (4) assess the impact of training on confidence and attitudes towards implementing training content and (5) collate qualitative feedback on helpful and unhelpful aspects of the training. We hypothesised that the training programmes would be well attended and accepted and would result in greater confidence and beliefs related to the content of the training. We explored qualitative feedback on helpful and unhelpful aspects of the training to inform future training initiatives.

Method

Design

Core training for the EYE-2 RCT occurred between January and July 2019 for staff in 20 EIP services across 9 NHS Trusts and 5 regions in the UK: London, Thames Valley, Hampshire, Cambridge-Norfolk and Manchester. All staff from participating services in each site were trained together. Two rounds of training were offered at each site to enable staff to attend training while maintaining service delivery, and to accommodate leave and absence. Any staff who are unable to attend all or part of their allocated training were asked to attend training at an alternative site.

Training dates and randomisation of services to study arms occurred well in advance of training to enable staff to plan to attend. Staff from all services at each site, randomised to both TAU and EYE-2 intervention arms, received a half-day training on robust collection of data from routine outcome measures. Staff from services randomised to the EYE-2 intervention arm remained for an additional one and a half days to receive training on the intervention approach. Thus, staff from TAU services received a half-day training programme and staff from intervention services received 2 full days of training.

Evaluation of training programmes employed a pre–post self-report survey design, with staff completing surveys immediately before and after training. Informed consent was obtained from staff prior to the start of the training.

Participants

Sample size was pragmatic and determined by how many staff could attend. Before starting the trial, each team was required to meet a minimum threshold of staff attendance; at least 70% of the entire team and at least 80% of care co-ordinators or team leads were required to attend training.

All staff from the 20 participating EIP services were invited to attend training. Participating services met the following inclusion criteria: (1) from a standalone EIP site with at least two discrete services, (2) willingness and capacity for involvement as agreed by clinical services, (3) identified site principal investigator with academic track record in leading RCTs in psychosis, (4) regional EIP support, (5) individual service size of at least 35–40 new clearly defined first-episode psychosis cases per year aged 14–35 years, (6) capturing NHS England mandated routine outcome data, (7) information technology and staff systems in place to increase routine outcome data capture and (8) geographical spread to include urban and rural locations, ethnic minority variations, and the North and South of England.

Training programmes

Both the one-and-a-half-day EYE-2 intervention training programme and half-day data collection training programme were led by the chief investigator of the project who developed the intervention and co-delivered by local patient and public involvement (PPI) leads, service users and carers. Rather than sessions being entirely instructive, training used a consultative approach and emphasised active learning, with the trainer working together with staff to generate ideas and apply learning to their services and caseloads. Training methods included interactive teaching sessions, group discussions, handouts, videos, booklets and role play. Both training programmes were supported by training manuals.

EYE-2 intervention training. Only staff from services randomised to the EYE-2 intervention arm received training on the intervention approach. The content of the intervention training programme was developed based on pilot work which identified the barriers and facilitators to Early Youth Engagement with EIP services from the perspective of young psychosis service users, families and young people not currently using services. The training programme was informed by previous work including interviews with EIP managers and clinicians in Sussex which identified the relationships between intervention components and service-level systemic factors that may impact implementation and interviews with service users from main regional ethnic minority and other minority populations to ensure that staff feel confident in working with culturally sensitive issues and service users from minority populations.

The intervention training programme included a wide range of modules to improve communication with young people, their families, and wider social network, to promote engagement with treatments, and to encourage the realisation of the young person's goals. Core sessions included: (1) introduction to the EYE-2 intervention and resources, (2) value of hopeful care co-ordination, (3) goal-focused care planning, (4) service user-led introduction to honest open communication, (5) carers' rights and family and friends protocol, (6) peer workers and social groups, (7) motivational interviewing for goal-focused engagement, (8) applying open communication approaches in the context of risk, risk taking, mental health exacerbations, treatment, and admissions, (9) social networks and open dialogue, (10) introducing the EYE-2 booklets and website and (11) implementation, barriers, and solutions.

Data collecting training. Staff from all services at each site, randomised to both TAU and EYE-2 intervention arms, received training on robust collection of data from NHS England-mandated routine outcome measures. The routine data comprise: (1) the clinician-rated Health of the Nation Outcome Scales (HoNOS; Wing *et al.*, 1998), which captures mental health and social and occupational functioning, (2) the patient-reported Questionnaire on the Process of Recovery (QPR; Law *et al.*, 2014), which measures recovery and (3) the patient-reported DIALOG measure of service satisfaction and quality of life (Priebe *et al.*, 2007). The aims of this training programme for all staff were to facilitate greater understanding of these measures, increase staff confidence in introducing and administering these measures and maximise data completeness for the RCT.

The training drew on self-affirmation theory. After a general introduction to the EYE study, staff undertook an exercise to identify personal and team values and consider the relationship between these values and the collection of patient-reported routine outcome data (QPR and DIALOG). They were then provided with an introduction to the measures, and completed additional exercises in teams, to identify barriers to data collection and potential solutions to support data collection locally. Additional exercises explored how to introduce the measures to service users and how to use them

to inform care planning. Care was taken to consider use of the measures in line with staff and team values. Finally, staff were presented with information and resources that were developed to support data collection. The resources included posters, goal-setting sheet for data collection, service user feedback report, and a spreadsheet for collecting data and generating graphs and reports.

Evaluation

Training programmes were evaluated using self-report paper questionnaires administered to staff immediately before and after training. The questions included, detailed below, were designed by the research team to evaluate items specific to the training programmes, for which no previous questionnaires were available.

Intervention training evaluation. Key outcomes were rate of attendance at training, staff experiences of the training, changes in confidence in using a range of EYE-2 engagement approaches, attitudes towards implementing the intervention, and qualitative feedback on helpful and unhelpful aspects of the training.

Experiences of the training. This was assessed using 15 questions asking staff how helpful they found each section of the training, on a seven-point Likert scale from 1 (not at all helpful) to 7 (very helpful). These questions were asked post training only. Sample sections of the training include: 'Hearing about local service user and carer perspectives on engagement' and 'Introducing the EYE-2 booklets'. Post-training Cronbach's alpha for all 15 items was 0.94.

Confidence in using a range of EYE-2 engagement approaches. Staff rated 10 questions assessing how confident they feel in using a range of engagement approaches, on a seven-point Likert scale from 1 (not at all confident) to 7 (very confident). These questions were asked pre and post training. Sample questions include: 'How confident do you feel in building a hopeful therapeutic relationship with a service user?' and 'How confident do you feel about using open dialogue approaches that are relevant to EIP?'. Baseline Cronbach's alpha for all 10 items was 0.89.

Attitudes towards implementing the intervention. This was measured using seven questions asking staff about their attitudes towards implementing the intervention, on a seven-point Likert scale from 1 (not at all or not at all confident/important/helpful/consistent) to 7 (all the time or very confident/important/helpful/consistent). These questions were asked post training only. Sample questions include: 'How helpful are the EYE-2 intervention and resources to your work?' and 'How much do you expect you will use the EYE-2 approach and resources?'. Post-training Cronbach's alpha for all seven items was 0.91.

Helpful and unhelpful aspects of the training. Qualitative feedback on helpful and unhelpful aspects of the training was gathered using open text boxes in response to two questions asked post training: (1) 'Is there anything that you found helpful or you particularly liked about the session?' and (2) 'Is there anything that you found unhelpful or that you think we should change about the session?'.

Data collection training evaluation. Key outcomes were rate of attendance at training, staff experiences of the training, changes in confidence in collecting outcome data, changes in beliefs about the importance of collecting outcome data, likelihood of collecting outcome data following training, and qualitative feedback on helpful and unhelpful aspects of the training.

Experiences of the training. This was assessed using seven questions asking staff how helpful they found each section of the training, on a seven-point Likert scale from 1 (not at all helpful) to 7 (very helpful). These questions were asked post training only. Sample sections of training include: 'Team values, routine measures, and why to collect them' and 'Introducing the measures to service users, using the measures to guide intervention and care-planning'. Post-training Cronbach's alpha for all seven items was 0.93.

Confidence in collecting outcome data. Staff rated two items relating to their confidence in collecting QPR and DIALOG outcome data, on a seven-point Likert scale from 1 (not at all confident) to 7 (very confident). These questions were asked pre and post training. Questions were: 'How confident do you feel about collecting the QPR measures?' and 'How confident do you feel about collecting the DIALOG measures?'. Baseline Cronbach's alpha for both items was 0.93.

Beliefs about the importance of collecting outcome data. Staff rated four items relating to their beliefs about the importance of collecting outcome data, on a seven-point Likert scale from 1 (not at all important) to 7 (very important). These questions were asked pre and post training. Sample questions include: 'How important do you think it is for your team to collect the QPR measure?' and 'How important do you think it is for you to collect the DIALOG measure?'. Baseline Cronbach's alpha for all four items was 0.91.

Likelihood of collecting outcome data following training. Staff were asked to rate how likely they were to use the QPR and DIALOG in routine practice following training, on a seven-point Likert scale from 1 (not at all likely) to 7 (very likely). These questions were asked post training only. Questions were: 'How likely will you be to use the QPR now in routine practice?' and 'How likely will you be to use the DIALOG now in routine practice?'. Post-training Cronbach's alpha for both items was 0.99.

Helpful and unhelpful aspects of the training. Qualitative feedback on helpful and unhelpful aspects of the training was gathered using open text boxes in response to the following questions asked post training: (1) 'Is there anything that you found helpful or you particularly liked about the session?' and (2) 'Is there anything that you found unhelpful or that you think we should change about the session?'.

Data analyses

Mean, standard deviation and range were reported for quantitative data. For outcomes collected both pre and post training (confidence in using a range of EYE-2 engagement approaches, confidence in collecting outcome data, and beliefs about the importance of collecting outcome data), data were analysed using mixed-effects models, with time as the independent variable and person and training group as random effects. We calculated intraclass correlation coefficients (ICCs) to measure the degree of clustering.

Qualitative data from both training programmes were analysed systematically using thematic analysis, as described by Braun and Clarke (2006), in NVivo version 12.5.0. Thematic analysis was used to identify and analyse themes inductively from the data.

Results

Participant attendance, survey completion and characteristics

A total of 462 staff working in the 20 participating EIP services were invited to attend training; 190 were invited to attend the data collection training only (from services randomised to the TAU arm) and 272 to attend both the data collection and intervention training (from services randomised to the EYE-2 intervention arm). Of the total number of staff working within teams, 427 (92.42%) consented to take part in training (175/92.11% from teams randomised to TAU and 252/92.65% from teams randomised to intervention) and 336 (72.73%) attended training (132/69.47% from teams randomised to TAU and 204/75% from teams randomised to intervention).

Of the 224 care co-ordinators or team leads across the 20 teams (87 from teams randomised to TAU and 137 from teams randomised to intervention), 187 (83.48%) attended training; 71 (81.61%) from teams randomised to TAU and 116 (84.67%) from teams randomised to intervention. Attendance rates met the minimum threshold of staff attendance set for teams of at least 70% of the entire team and at least 80% of care co-ordinators or team leads required to attend training.

Of the 336 staff who attended the data collection training, 282 (83.93%) completed the pre-training survey, 284 (84.52%) completed the post-training survey and 281 (83.63%) returned both pre- and post-training surveys. Of the 204 staff who attended the intervention training, 174 (85.29%) completed the pre-training survey, 183 (89.71%) completed the post-training second-day survey and 159 (77.94%) returned both pre- and post-training surveys.

Demographic and mean data reported are based on the available data from all staff who completed pre-training or post-training surveys, while statistical analyses are based only on available data from those who completed both pre- and post-training surveys. *Table 1* presents the baseline demographic characteristics of all staff who attended the

training programmes and completed demographic survey questions. The mean age was 38.24 (SD = 10.14) years for the intervention training and 38.96 (SD = 10.41) for the data collection training. The majority of staff were female (74.1% in intervention training; 76.5% in data collection training) and white (84.8% in intervention training; 80.6% in data collection training). In terms of core discipline or role, 40.6%–41.5% were nurses, 16.5%–17.0% were social workers, 9.8%–10.1% were occupational therapists, and 11.4%–11.7% were psychologists. The remaining disciplines and roles comprised < 6% of the samples.

Quantitative findings

Intervention training. Descriptive data and statistical analyses for outcomes from the intervention training are shown in *Table 2*.

Experiences of the training. On average, the intervention training material was rated moderately high in terms of helpfulness, with a post-training mean rating of 5.83 (SD = 0.65, range = 3.33–7) out of 7.

Confidence in using a range of EYE-2 engagement approaches. There was an effect of time (pre training, post training) in improving in self-reported confidence in using a range of EYE-2 engagement approaches, $b = 0.72$, $t(162.93) = 13.67$, $p < 0.001$. ICC was large for person (ICC = 0.61) and small for training group (ICC = 0.13), indicating that 13% of the total variation in the confidence variable can be accounted for by the training group staff attended and 61% of the total variation in the confidence variable can be attributed to differences between staff.

Attitudes towards implementing the intervention. On average, staff attitudes towards implementing the intervention following the training were highly positive, with a mean rating of 5.88 (SD = 0.74, range = 3.43–7) out of 7.

Data collection training. Descriptive data and statistical analyses for outcomes from the data collection training are shown in *Table 2*.

Experiences of the training. On average, the data collection training material was rated moderately high in terms of helpfulness, with a post-training mean rating of 5.84 (SD = 0.86, range = 2.57–7) out of 7.

Confidence in collecting outcome data. There was an effect of time (pre training, post training) in improving self-reported confidence in collecting outcome data, $b = 1.33$, $t(268.47) = 15.94$, $p < 0.001$. ICC was large for person (ICC = 0.54) and small for training group (ICC = 0.11), indicating that 11% of the total variation in confidence in collecting outcome data can be accounted for by the training group staff attended and 54% of the total variation in confidence can be attributed to differences between staff.

Beliefs about the importance of collecting outcome data. There was an effect of time (pre training, post training) in improving self-reported beliefs about the importance of collecting outcome data, $b = 0.78$, $t(268.74) = 11.85$, $p < 0.001$. ICC was large for person (ICC = 0.51) and small for training group (ICC = 0.07), indicating that just 7% of the total variation in confidence in collecting outcome data can be accounted for by the training group staff attended and half of the total variation in confidence can be attributed to differences between staff.

Likelihood of collecting outcome data following training. On average, staff reported a high likelihood of collecting QPR and DIALOG data following training, with a mean rating of 6.08 (SD = 1.23, range = 1–7) out of 7.

Qualitative findings

Four overarching themes of helpful and unhelpful aspects were identified for both training programmes: (1) Preferred approaches to training, (2) Preferred content of training, (3) Application to and impact on clinical practice and (4) Useful resources. These are discussed below with illustrative quotes.

Preferred approaches to training. Staff were positive about the general training approach and the quality of training delivery. The consultative approach to training, with the trainer working together with staff to generate ideas and apply learning to their caseloads, was well-received and viewed as helpful: 'positive approach, positive feedback, ideas of "consultation" and "training"'. Staff also commented on the relevance of the training for their work and were positive

TABLE 39 Baseline demographic characteristics of all staff who attended the training programmes and completed demographic survey questions

	Intervention training (*N* = 197)		Data collection training (*N* = 282)	
	M (SD)	Range	*M* (SD)	Range
Age	38.24 (10.14)	20–77	38.96 (10.41)	18–67
Gender	*n*	%	*n*	%
Female	143	74.1	215	76.5
Male	50	25.9	65	23.1
Ethnicity				
White	162	84.8	224	80.6
Black British	8	4.2	11	4.0
Black African/Afro-Caribbean	9	4.7	21	7.6
Asian	7	3.7	10	3.6
Mixed	5	2.6	8	2.9
Other	–	–	4	1.4
Core discipline/role				
Nurse	78	41.5	107	40.6
Social worker	31	16.5	45	17.0
Occupational therapist	19	10.1	26	9.8
Support, time and recovery worker	7	3.7	14	5.3
Psychologist	22	11.7	30	11.4
Psychiatrist	10	5.3	11	4.2
Administrator	1	0.5	4	1.5
MSc student	1	0.5	1	0.4
Student nurse	3	1.6	8	3.0
Trainee psychologist	2	1.1	4	1.5
Pharmacist	1	0.5	2	0.8
Individual placement and support specialist	1	0.5	–	–
RA	1	0.5	–	–
Assistant practitioner	3	1.6	1	0.4
Support worker	7	3.7	11	4.2
Vocational	1	0.5	–	–

about the delivery: 'This is a great training that really does feel connected with the reality of EI practice. [Trainer name] really conveyed a great set of values'.

Service user involvement. Many staff found it helpful that the training was co-delivered by service users and carers and commented on the value of service user involvement: 'the perspectives and experiences of the two service users was very welcomed'. Staff felt that service user involvement was helpful in terms of learning about barriers to engagement in services and how to overcome these in their work: 'I found the service users involvement particularly insightful of

TABLE 40 Raw descriptive data for outcomes from the intervention and data collection training programmes at pre training and/or post training

	Pre training		Post training	
	M (SD); range	*N*	*M* (SD); range	*N*
Intervention training				
Experiences of training	–	–	5.83 (0.65); 3.33–7	90
Confidence in using EYE-2 engagement approaches	5.08 (0.82); 1.90–6.90	168	5.83 (0.65); 3.10–7	172
Attitudes towards implementation	–	–	5.88 (0.74); 3.43–7	166
Data collection training				
Experiences of training	–	–	5.84 (0.86); 2.57–7	267
Confidence in collecting data	4.76 (1.72); 1–7	279	6.10 (1.00); 1–7	267
Beliefs about the importance of collecting data	5.53 (1.23); 1–7	275	6.32 (0.90); 2–7	267
Likelihood of collecting data	–	–	6.08 (1.23); 1–7	263

difficult experiences under EI and a snippet of the challenges they have had and what EI need to be dealing with' and 'it was very helpful to learn about service user experiences and to learn that they were fully involved in the development of the programme. It makes me feel more confident about delivering EI interventions'. This approach to training was so valued that a few staff suggested 'more service user involvement' in future training.

Sharing experiences through discussion. Many staff commended the collaborative approach to training and liked that sessions were 'interactive and considered everyone's contributions'. They expressed that it was helpful to hear the experiences of, and share ideas with, other teams in the area: 'to gain insight into how other teams experience the same barriers in their practice through discussion'. Staff also reported that they found it helpful to have discussions within their own team: 'team discussions – it helped me to better understand different opinions in the team'. Suggestions for changes to training include 'more opportunities for discussion' and for training to be even 'more interactive'.

Enhanced personal knowledge

Greater understanding of outcome measures. Following data collection training, staff reported having a better understanding of the routine outcomes measures and the purpose of collecting these data: '. . . give[s] some meaning/purpose to completing the measures instead of going through the motions' and 'explaining what the questions actually mean'. The rationale for collecting routine data appears not to have previously been explained to some staff, with one person commenting that: 'I've worked in my team for two years and this is the first time anyone had bothered to talk to me about them'. Moreover, a few people expressed 'wanting more explanation around measures and rationale'. However, this was not a view shared by everyone, with a few people stating that they were already familiar with the content of the data collection training: '[Trust name] have been using the measures for years so teams are familiar with this'.

Better understanding of the project. At the start of the data collection training programme, the context to the training was set by informing staff of the previous findings from the EYE project which developed the EYE-2 intervention. This element was generally well-received, with staff commenting that: 'it was good to hear about EYE and how this has informed EYE-2' and '[there was the] opportunity to ask questions and understand the research project as a whole including purpose and aims'. In addition to a better understanding of the roots of the project and intervention, staff seemed to value being involved in research: 'good to be involved in national research and think about engagement'. Although staff generally found the background to the project and intervention helpful, some stated that: 'less time [was] needed [for] discussing overall research project'.

Refresher on motivational interviewing. Many staff who attended the intervention training reported finding the refresher on motivational interviewing helpful: 'MI recap was so useful!' and 'really helpful "top up"/reminder of skills around MI'. Staff appeared to vary in how much motivational interviewing training they previously received, with some expressing wanting additional time on motivational interviewing – 'some additional time on motivational interviewing could have been helpful' and 'would have liked more on MI techniques' – and others commenting that they needed less time on this part of the training: 'less information about motivational interviewing and collaboration and risk as we already have training on this'.

Reflecting on values. Staff were positive about the values exercise, in which they identified and reflected on personal and team values and considered the relationship between these values and their work. One person commented that it was 'just good to get back to values and focus on what is important'. Others noted its relevance to their work: 'looking at own values and how they affect our professional approach' and 'I enjoyed the open activity about our own values and how this impacts our expectations'.

Application to and impact on clinical practice

Informing care plans and practice. Many staff found learning about the routine outcome measures helpful in terms of informing care plans and building a therapeutic relationship with service users. Staff stated that they valued 'ideas about positively using QPR and DIALOG to inform care plans' and 'reflecting on the clinical value of the QPR and DIALOG'. Staff felt that a better understanding of the measures was valuable in terms of building a positive therapeutic alliance: 'using the DIALOG as a tool for building a therapeutic relationship'. One person reported that: 'I have an improved understanding on the outcome measurement tools and the reason behind their use as a data collection tool and how they can be used improving patients' engagement with care delivery'.

Overcoming barriers to implementing outcome measures. Staff generally reported that a helpful exercise in the data collection training was 'discussing barriers to data collection and how to overcome them' and the 'opportunity for discussion around barriers and solutions to implementing measures'. A few people commented that it would be helpful to have spent more time on this part of the training: 'more examples of tried and tested ways to improve data collection' and 'it would have been good to have a bit more time on overcoming barriers'.

Using motivational interviewing in practice. In general, staff appeared to value parts of the intervention training which explored how motivational interviewing can be applied to clinical practice. One staff member commented that they valued 'the scenarios . . . [they gave] us room to explore how MI would work in risk management scenarios'. Others agreed that this was a helpful aspect of the training: 'motivational interviewing and risk – often difficult to address in practice so useful to discuss' and 'the MI videos . . . most brought to life what the intervention should look like'. However, some staff appeared to be more confident with applying motivational interviewing techniques to their clinical practice and commented that less time was needed for this exercise: '[I] did not find communication/MI techniques helpful as already use these' and 'I felt that the open dialogue and MI recap was helpful but I also found that a lot of the discussion is what we already strive to do as a team'.

Implementing social groups. Staff who attended the intervention training expressed that reflecting on and discussing how social groups would be implemented in their services was helpful: 'thinking about barriers to implementing peer support groups' and 'discussion re: implementing social groups'.

'The useful resources'. The data collection training provided staff with tools to assist them with the collection of data from routine outcome measures. Staff reported finding 'exploring the tools' helpful, in particular the 'attractive user-friendly manual' and 'resources for creating graphs to compare questionnaire data'. Staff completing the intervention training gave positive feedback on the intervention materials and resources provided. One staff member expressed that they liked 'everything, especially booklets and website – all information easily accessible in one place'. Others commented that: 'loved looking at the booklets – would have liked longer on this', 'the booklets are great, really clear, well written and accessible' and 'love the booklets and website'. In addition to introducing the intervention materials, staff were given information on when and how to use the resources with service users and their social network in order to enhance engagement. One person fed back that it would be helpful to spend more time discussing how to implement these resources: 'more focus on how the booklets can be woven into engagement work'.

Discussion

The aim of the current study was to implement and evaluate training programmes for EIP staff as part of the cluster RCT comparing the EYE-2 intervention to TAU (Greenwood *et al.*, 2021). Specific objectives were to record staff attendance at training sessions, assess experiences of the training, assess the impact of training on confidence and attitudes towards implementing training content, and collate qualitative feedback.

Both training programmes were well-attended. Training was delivered to 336 staff working across 20 EIP services (72.73% of total staff employed) in nine NHS Trusts and five regions in the UK: London, Thames Valley, Hampshire, Cambridge-Norfolk and Manchester. One hundred and thirty-two staff (69.47%) from teams randomised to the TAU arm of the RCT received training in robust collection of data from NHS England-mandated routine outcome measures and 204 staff (75%) from teams randomised to the intervention arm received training in both robust data collection and the EYE-2 intervention.

We collected data from 83.63% to 84.52% of staff as part of the data collection training and from 77.94% to 89.71% of staff as part of the intervention training. Both training programmes were well-accepted, with staff rating training material moderately high in terms of helpfulness. Consistent with our hypothesis, the training programmes led to increases in confidence in using EYE-2 engagement approaches and collecting outcome data. Attitudes were highly positive towards implementation of the EYE-2 intervention. The data collection training also led to increases in beliefs about the importance of collecting outcome data. Staff reported a high likelihood of collecting outcome data following training. These findings indicate that the training programmes resulted in improvements in staff competence in engaging young people with psychosis and collecting routine outcome data to continually assess their progress.

Thematic analysis of qualitative data identified four overarching themes of helpful and unhelpful aspects which were applicable to both training programmes. The first theme, Preferred approaches to training, highlighted that staff valued the general consultative approach to training, the delivery of training content, service user involvement in co-delivering training, and opportunities to share experiences through discussion with other teams and within their own team. The second theme related to preferred content of training and enhanced personal knowledge following training. Specifically, many staff expressed a greater understanding of outcome measures and the overall research project following data collection training. Staff also reported finding the refresher on motivational interviewing and reflecting on values helpful. The third theme encompassed aspects of training staff found to be helpful in terms of their application to and impact on clinical practice. In general, staff valued parts of the training which they perceived to help inform care plans, overcome barriers to implementing outcome measures, explore how to apply motivational interviewing skills, and guide the implementation of social groups. Finally, the last theme referred to the usefulness of the resources introduced in both training programmes, such as tools to assist with data collection and intervention materials.

Findings across all four themes indicate that aspects which staff found to be less helpful appeared to relate to individual differences in existing experiences, skills and knowledge prior to training. For example, in the second theme, Enhanced personal knowledge, the degree to which training led to a greater understanding and appreciation of outcome measures depended on how familiar they were with the measures; some expressed that they have not had a discussion on measures before and that they would value more explanation around measures, whereas others stated that they were already familiar with the measures. Similarly, in the third theme, Application to and impact on clinical practice, although staff generally valued exploring how motivational interviewing can be applied to practice, some staff seemed to be more confident in applying these skills to their practice and noted that less time was needed for this exercise. Individual differences in existing experiences, skills and knowledge may in part be attributable to differences in training provisions across teams. For example, in the Enhanced personal knowledge theme, one staff member suggested that less information on motivational interviewing was needed as they already have training on this. Yet, the fact that most staff commented on the usefulness of this refresher and some asked for more time on this suggests that not all teams receive regular or any refresher training on motivational interviewing techniques.

On the whole, staff appeared to value both training programmes and their approach, content, relevance to clinical practice, and resources, and current qualitative feedback on the training programmes has the potential to inform future training initiatives. These qualitative findings are consistent with the promising quantitative findings in terms of training

programmes being well-accepted and leading to improvements in confidence and in using engagement approaches and collecting outcome data. Taken together, this study adds to the limited research on EIP workforce training.

Limitations and future directions

The current study used an uncontrolled pre–post design to evaluate the training programmes. Inclusion of a non-training control group was not feasible, as training initiatives were embedded as part of a larger multisite cluster RCT and staff from all participating services were required to receive training. Despite this, given the uncontrolled design, findings should not be regarded as conclusive evidence supporting the effects of the training programmes.

An important goal of any training programme is increasing the implementation of training content in everyday practice. The current study did not collect follow-up data and only evaluated outcomes immediately following training. We are therefore unable to determine whether training resulted in the maintenance of confidence in, attitudes towards, and likelihood of practising training content, and the actual implementation of training content. However, it is important to note that these training programmes were delivered as part of a multisite cluster RCT which is currently underway. As part of the RCT, we aim to conduct a large-scale process evaluation to explore staff uptake and implementation of the intervention over time. It will therefore be possible to assess whether the training was successful in terms of implementation of training content in clinical practice. The training programme and intervention resources will also be refined following the outcome of the process evaluation.

We required each service to meet a minimum threshold of staff attendance before they could start in the RCT; at least 70% of the entire team and at least 80% of care co-ordinators or team leads were required to attend training. While this resulted in good attendance rates, we were not able to gather naturalistic data on the number of staff who would be motivated to undertake such training. Nevertheless, this attendance strategy was necessary for the implementation of the intervention and validity of the trial. Future workforce training initiatives embedded in research trials may consider adopting similar attendance thresholds to maximise the robustness of trial findings.

Implications for future implementation

There are implications of these findings for the delivery of future workforce training programmes. Current findings support the feasibility, acceptability and efficacy of brief training in robust collection of routine outcome data and intervention engagement approaches. Not only were we able to train a large proportion of staff from EIP services due to our attendance strategy, but our brief training programmes were well-accepted and resulted in positive outcomes, such as increases in confidence in using EYE-2 engagement approaches and collecting outcome data, and in beliefs about the importance of collecting outcome data. We hope that our training model may help inform, and contribute to the success of, future training initiatives.

Demonstrating the success of workforce training is a necessary prerequisite to the implementation of interventions in health service contexts and the current promising findings support the future implementation of the EYE-2 intervention in EIP services. Once the process evaluation, running alongside the EYE-2 RCT, is complete, we will have a better understanding of how the intervention is being implemented in EIP services. If the intervention is found to be effective and cost-effective, and implemented well in routine clinical practice, this would support national uptake of the EYE-2 intervention in EIP services and dissemination of the current training programmes. This would involve exploring ways of streamlining training, while maintaining its effectiveness, to further ensure feasibility and acceptability of delivering training to the entire EIP workforce. One possible model for training may be for staff who are already trained and experienced in delivering the EYE-2 intervention to train further staff and maintain the trained skills in their teams.

Conclusion

The current study aimed to deliver and evaluate training programmes for EIP staff as part of the cluster RCT comparing the EYE-2 intervention to TAU. Findings support the feasibility, acceptability and effectiveness of training EIP staff in robust collection of routine outcome data and intervention engagement approaches. Both data collection and intervention training programmes were well-attended and well-received, and led to improvements in staff confidence in, and attitudes towards, engaging young people with psychosis and collecting their routine outcome data to monitor progress. Qualitative feedback indicated that staff valued both training programmes and their approach, content, relevance to clinical practice and resources. Current findings contribute to the limited research on EIP workforce training and have the potential to inform future training initiatives.

References

1. Berry K, Haddock G. The implementation of the NICE guidelines for schizophrenia: Barriers to the implementation of psychological interventions and recommendations for the future. *Psychol Psychother* 2008;**81**:419–36.
2. Bertelsen M, Jeppesen P, Petersen L, Thorup A, ∅hlenschlæger J, Quach PL, *et al*. Suicidal behaviour and mortality in first episode psychosis: the OPUS trial. *Br J Psychiatry* 2007;**191**:s140–6.
3. Birchwood M, Todd P, Jackson C. Early Intervention in Psychosis: the critical period hypothesis. *Br J Psychiatry* 1998;**172**:53–9.
4. Birchwood M, Fiorillo A. The critical period for early intervention. *Psychiatr Rehabil Skills* 2000;**4**:182–98.
5. Bottlender R, *et al*. The impact of duration of untreated psychosis prior to first psychiatric admission on the 15-year outcome in schizophrenia. *Schizophrenia Res* 2003;**62**:37–44.
6. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101.
7. Conus P, Lambert M, Cotton S, Bonsack C, McGorry PD, Schimmelmann BG. Rate and predictors of service disengagement in an epidemiological first-episode psychosis cohort. *Schizophr Res* 2010;**118**:256–63.
8. DOH. *National Service Framework for Mental Health: Modern Standards and Service Models*. 1999. URL: www.gov.uk (accessed 18 February 2023).
9. Department of Health. *The NHS Plan: A Plan for Investment. A Plan for Reform*. London: The Stationery Office; 2000 (Cm. 4818-I).
10. Dodgson G, Crebbin K, Pickering C, Mitford E, Brabban A, Paxton R. Early Intervention in Psychosis service and psychiatric admissions. *Psychiatr Bull* 2008;**32**:413–6.
11. Doyle R, Turner N, Fanning F, Brennan D, Renwick L, Lawlor E, Clarke M. First episode psychosis and disengagement from treatment: a systematic review. *Psychiatr Serv* 2014;**65**:603–11.
12. Garety PA, Craig TK, Dunn G, Fornells-Ambrojo M, Colbert S, Rahaman N, *et al*. Specialized care for early psychosis: symptoms, social functioning, and patient satisfaction. *Br J Psychiatry* 2006;**188**:3745.
13. Greenwood K, Chandler R, Labuschagne K, Peters E, Alford K, de Visser R, *et al*. The development and piloting of an Early Youth-Engagement (EYE) model to improve engagement of young people in first episode psychosis services: a mixed methods study. *Early Interv Psychiatry* 2025 Jan;**19**(1):e13623. https://doi.org/10.1111/eip.13623. Epub 2024 Oct 22. PMID: 39435971.
14. Greenwood K, Webb R, Gu J, Fowler D, de Visser R, Bremner S, *et al*. The Early Youth Engagement in first episode psychosis (EYE-2) study: pragmatic cluster randomized controlled trial of implementation, effectiveness and cost-effectiveness of a team-based motivational engagement intervention to improve engagement. *Trials* 2021;**22**:272. https://doi.org/10.1186/s13063-021-05105-y
15. Harris M, Henry L, Lockwood A, *et al*. The relationship between duration of untreated psychosis and outcome: an 8-year prospective study. *Schizophr Res* 2005;**79**:85–93.

16. Harris MG, Burgess PM, Chant DC, Pirkis JE, McGorry PD. Impact of a specialized early psychosis treatment programme on suicide. Retrospective cohort study. *Early Interv Psychiatry* 2008;**2**:11–21.

17. Law H, Neil ST, Dunn G, Morrison AP. Psychometric properties of the questionnaire about the process of recovery (QPR). *Schizophrenia Res* 2014;**156**:184–9.

18. Marshall M, Lewis S, Lockwood A, Drake R, Jones P, Croudace T. Association between duration of untreated psychosis and outcome in cohorts of first-episode patients: a systematic review. *Arch Gen Psychiatry* 2005;**62**:975–83.

19. McCrone P, Craig T, Power P, Garety P. Cost-effectiveness of an early intervention service for people with psychosis. *Br J Psychiatry* 2010;**196**:377–82.

20. McCrone P, Craig T, Power P, Garety P. Cost-effectiveness of an early intervention service for people with psychosis. *Br J Psychiatry* 2010;**196**:377–82.

21. Melle I, Johannesen JO, Friis S, Haahr U, Joa I, Larsen TK, *et al*. Early detection of the first episode of schizophrenia and suicidal behavior. *Am J Psychiatry* 2006;**163**:800–4.

22. Mihalopoulos C, Harris M, Henry L, Harrigan S, McGorry P. Is Early Intervention in Psychosis cost-effective over the long term? *Schizophr Bull* 2009;**35**:909–18.

23. Nordentoft M, Jeppesen P, Abel M, *et al*. OPUS study: suicidal behavior, suicidal ideation and hopelessness among patients with first -episode psychosis. *Br J Psychiatry* 2002;**181**:98–106.

24. NHS England, the National Collaborating Centre for Mental Health, & the National Institute for Health and Care Excellence. *Implementing the Early Intervention in Psychosis Access and Waiting Time Standard: Guidance*. 2016. URL: www.england.nhs.uk/mentalhealth/wp-content/uploads/sites/29/2016/04/eip-guidance.pdf (accessed 18 February 2023).

25. NHS England. *Implementing the Five Year Forward View for Mental Health*. 2016. URL: https://www.england.nhs.uk/publication/implementing-the-fyfv-for-mental-health/ (accessed 18 February 2023).

26. Pelosi AJ, Birchwood M. Is Early Intervention in Psychosis a waste of valuable resources? *Br J Psychiatry* 2003;**182**:196–8.

27. Priebe S, McCABE R, Bullenkamp J, Hansson L, Lauber C, Martinez-Leal R, *et al*. Structured patient–clinician communication and 1-year outcome in community mental healthcare: cluster randomised controlled trial. *Br J Psychiatry* 2007;**191**:420–6.

28. Renju J, Birchwood M. The national policy reforms for mental health services and the story of early intervention services in the United Kingdom. *J Psychiatry Neurosci* 2005;**30**:362–5.

29. Rossler W, Salize HJ, van Os J, Riecher-Rössler A. Size of burden of schizophrenia and psychotic disorders. *Eur Neuropsychopharmacol* 2005;**15**:399–409.

30. Royal College of Psychiatrists. *Early Intervention in Psychosis Network Self-Assessment Tool Guidance. 2016. College Centre for Quality Improvement*. London: Royal College of Psychiatrists; 2016.

31. Sartorius N, Jablensky A, Korten A, Ernberg G, Anker M, Cooper JE, Day R. Early manifestations and first-contact incidence of schizophrenia in different cultures. A preliminary report on the initial evaluation phase of the WHO Collaborative Study on determinants of outcome of severe mental disorders. *Psychol Med* 1986;**16**:909–28.

32. Shafran R, Clark DM, Fairburn CG, Arntz A, Barlow DH, Ehlers A, *et al*. Mind the gap: improving the dissemination of CBT. *Behav Res Ther* 2009;**47**:902–9. https://doi.org/10.1016/j.brat.2009.07.003. Epub 2009 Aug 6. PMID: 19664756

33. Tait L, Birchwood M, Trower P. Predicting engagement with services for psychosis: insight, symptoms, and recovery style. *Br J Psychiatry* 2003;**182**:123–8.

34. The Schizophrenia Commission. *The Abandoned Illness: A Report from the Schizophrenia Commission*. 2012. URL: https://www.rethink.org/media/2637/the-abandoned-illness-final.pdf (accessed 18 February 2023).

35. Turner M, Smith-Hamel C, Mulder R. Prediction of twelve-month service disengagement from an Early Intervention in Psychosis service. *Early Interv Psychiatry* 2007;**1**:276–81.

36. Wiersma D, Nienhuis F, Slooff C, *et al*. Natural course of schizophrenic disorders: a 15-year followup of a Dutch incidence cohort. *Schizophr Bull* 1998;**24**:75–85.

37. Wing JK, Beevor AS, Curtis RH, Park SB, Hadden S, Burns A. Health of the Nation Outcome Scales (HoNOS) Research and development. *Br J Psychiatry* 1998;**172**:11–8. https://doi.org/10.1192/bjp.172.1.11

38. World Health Organization & International Early Psychosis Association. *Early Psychosis Declaration: An International Consensus Statement about Early Intervention and Recovery for Young People with Early Psychosis*. 2004.

Appendix 6 Additional tables from the health economic analysis

TABLE 41 Social outcomes across groups

	Mean number of days over 12 months	SD	*N* (% of those interviewed with incomplete data)
Stable independent living arrangements	237	143	206 (11%)
Paid and unpaid employment	52	102	223 (4%)
Education and training	89	119	220 (5%)

Results from the sensitivity analysis (adjustments made for participants who entered the study pre- or post-national lockdown) are presented in *Table 42*. For ease of comparison, base results are presented in parentheses. These adjustments made little difference to cost comparisons between arms.

TABLE 42 Sensitivity analysis: adjusting for effect of COVID-19 pandemic

	Adjusted difference in mean cost (expected value)	95% CI	Probability of higher cost within population
Planned contacts	−£1200 (−£1280)	−£172 to £124 (−£173 to £122)	41% (40%)
Unplanned contacts	−£24 (−£25)	−£4117 to £1717 (−£4126 to £1565	21% (19%)
Total societal cost	−£896 (−£526)	−£6519 to £4726 (−£7031 to £5980)	49% (43%)

TABLE 43 Unit cost table, all costs are inflated to year 2021–2 using the NHS cost inflation index (NHSCII) allowing for a more granular adjusted cost analysis within mental health service categories

Service	£ Great British pounds	Source
Mental Health Services – case notes		
Mental health admission (bed-day)	445.98	PSSRU 2010
Crisis contacts		
A&E Mental Health Liaison Services (attendance)	253.76	Reference Cost Year 2019–20
Mental Health Act assessment (occurrence)	1308.92	Heslin *et al.*
Section 136 suite (occurrence)	1715.57	Heslin *et al.*
Ambulance, see and treat and convey (occurrence)	310.49	Reference Cost Year 2019–20
Ambulance, convey (occurrence)	226.42	Reference Cost Year 2019–20
Crisis resolution teams (per hour)	36.92	PSSRU 2010
EIP		
Psychiatrist (per hour)	77.33	PSSRU 2020–1
Psychologist (per hour)	77.33	PSSRU 2020–1

continued

TABLE 43 Unit cost table, all costs are inflated to year 2021/22 using the NHS cost inflation index (NHSCII) allowing for a more granular adjusted cost analysis within mental health service categories (*continued*)

Service	£ Great British pounds	Source
Mental health nurse (per hour)	55.67	PSSRU 2020–1
Occupational therapist	55.67	PSSRU 2020–1
Social worker	55.67	PSSRU 2020–1
Support worker	27.84	PSSRU 2020–1
Vocational worker	42.27	PSSRU 2020–1
CBT therapist	67.02	PSSRU 2020–1
Family therapist	67.02	PSSRU 2020–1
Pharmacist	77.33	PSSRU 2020–1
Psychology assistant	36.09	PSSRU 2020–1
Non-mental health – self completed		
Community – NHS		
GP visit	40.10	PSSRU 2020–1
Practice nurse visit	19.18	PSSRU 2015–6[a]
Walk-in centre	86.00	Reference Cost Year 2019–20
NHS direct/NHS psychiatric helpline	7.00	PSSRU 2015–6
Daycentre per client	39.00	PSSRU 2020–1
Community non-NHS		
Day-centre private	50.00	www.starsdaycare.co.uk[b]
Counsellor non-NHS		www.nhs.uk[c]
Psychotherapist non-NHS (session)	75.00	www.privatehealth.co.uk[d]
Psychiatrist non-NHS (session)	300.00	www.health-private.co.uk[e]
Police contacts		
Contact with the police due to being a victim	267.00	Heslin *et al.*[f]
Arrested under suspicion of committing a criminal offence	457.00	Heslin *et al.*
Accommodation		
Homeless: hostel, shelter or refuge (per week)	155.00	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/214489/rrep714.pdf[g]
Care homes – local authority (per resident per week)	867.00	PSSRU 2020/21
Hospital contacts		
Elective inpatient admission – physical (bed-days)	4334.91	Reference Cost Year 2019–20
Day-case	799.38	Reference Cost Year 2019–20
Non-elective short stay (bed-days)	852.53	Reference Cost Year 2019–20

TABLE 43 Unit cost table, all costs are inflated to year 2021/22 using the NHS cost inflation index (NHSCII) allowing for a more granular adjusted cost analysis within mental health service categories (*continued*)

Service	£ Great British pounds	Source
Non-elective long stay (bed-days)	3740.70	Reference Cost Year 2019–20
Hospital outpatient clinic – physical (attendance)	148.00	Reference Cost Year 2019–20
A&E – walk-in (attendance)	166.00	Reference Cost Year 2019–20
A&E – with ambulance (attendance)	292.09	Reference Cost Year 2019–20

a Curtis L, Burns A. *Unit Costs of Health and Social Care. 2020*. URL: www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2015/ (accessed 10 June 2022).
b *Services and Price List*. stars. n.d.. URL:www.starsdaycare.co.uk/price-list (accessed 10 June 2022).
c NHS. *NHS Choices*. n.d. URL: www.nhs.uk/mental-health/talking-therapies-medicine-treatments/talking-therapies-and-counselling/counselling/ (accessed 10 June 2022).
d *Private Healthcare UK*. n.d.. URL: www.privatehealth.co.uk/conditions-and-treatments/consultation-with-a-psychotherapist/costs/ (accessed 10 June 2022).
e *Health Private*. 23 July 2021. URL: www.health-private.co.uk/fees/ (accessed 10 June 2022).
f Heslin M, Callaghan L, Barrett B, Lea S, Eick S, Morgan J, *et al.* Costs of the police service and mental healthcare pathways experienced by individuals with enduring mental health needs. *Br J Psychiatry* 2017;**210**:157–64.
g Boath M, Baker E, Wilkinson H. (rep.). *'Exempt' and Supported Accommodation* (pp. 1–114). London: Department for Work and Pensions; 2010.

TABLE 44 Cost of mental health service contacts by service type: adjusted difference

	Adjusted difference in mean cost (£)	95% CI	*N*
Planned care contacts			
Medication	20	−£91 to £132	628
EiP service contacts	−46	−£202 to £110	947
Unplanned care contacts			
Cost of psychiatric bed-day utilisation	−1317	−£4004 to £1369	945
Cost of psychiatric A&E contacts	−5	−£50 to £40	880
Cost of Mental Health Act assessment	−153	−£386 to £80	840
Cost of Section 136 suite utilisation	−405	−£576 to £1387	820
Cost of crisis ambulance utilisation	21	−£23 to £65	862
Cost of Crisis resolution team contact	−35	−£102 to £32	932

Note
Adjusted differences based on complete case analysis.

Appendix 7 A detailed summary of the content of training and implementation questionnaires and qualitative interview topic guides

The Early Youth Engagement-2/Early Intervention in Psychosis service delivery questionnaire

The questionnaires aimed to evaluate adherence to the EIP and EYE-2 intervention models, individual and team policies and practices.

The questionnaire incorporates EIP/EYE-2 checklists, and the NOMAD tool[63] which explores attitudes and behaviours towards implementation based on normalisation process theory (NPT). Specifically, the EYE-2 questionnaire and EIP questionnaire included questions related to:

Context

- Six questions on the impact of COVID-19 on use of EYE-2 resources from 1 (severely negatively impacted to 7 (severely positively impacted) (second and third rounds only and not included in EIP version).
- Ten questions on the impact of COVID-19 (PPE, reduced F2F contact, video-consultation, workload pressure) and other factors (team views, service user insight, reading ability, service user feedback, own ability and own confidence) on engagement approaches [first 4 COVID-19 questions included in EIP version].

Mechanisms and processes

- The clinician-rated NOMAD tool which incorporates four questions on coherence, four on cognitive participation, seven on collective action and five on reflexive monitoring each rated from 1 (strongly agree) to 5 (strongly disagree). Additional questions ask about the extent to which the EYE-2 is familiar, part of current practice and expected to be part of future practice, each rated from 0 (not at all) to 10 (completely) (not included in EIP version).
- Three questions on the value of the training rated 1(not at all helpful) to 7 (very helpful) [not included in EIP version].
- Three questions on sense of pride, confidence and professionalism in using EYE-2 from 1 (strongly disagree) to 5 (strongly agree) [not included in EIP version].
- Nine to eleven questions on confidence in using a variety of EYE-2 approaches from 1 (not at all) to 7 (very confident) (9–11 for EIP version, asked generically).
- Three questions plus space to record other training, regarding training experiences since the trial start, rated on a seven-point scale from not at all, to 5 + days training received (included in EIP version).

Intervention outcomes

- Seven questions on whether EYE-2 *approaches* were used over the previous 6 months with EYE-2 service users, rated from 1 (not using at all) to 5 (using in 76–100% of sessions) (EIP version asked generically).
- Twelve questions on whether EYE-2 *resources* were used over the previous 6 months with EYE-2 service users, rated from 1 (not using at all) to 5 (using in 76–100% of sessions) (not included in EIP version).
- Six to seven questions on whether or how frequently EYE-2 *resources were used by the individual or within their team* rated from 1 (not at all) to 5 (weekly) (not included in EIP version).
- The clinician-rated Working Alliance Inventory – 12 questions which cover therapeutic goals, bonds and tasks each rated 1 (never) to 7 (always) (included in EIP version).
- People were also asked to record social groups offered and their demographic details (included in EIP version).
- Five questions in the EIP version only asked about inadvertent access to and use of the EYE-2 resources (contamination).

The EYE-2 questionnaire was used to describe a threshold for effective implementation based on clinicians' use of EYE-2 resources with EYE-2 service users. A composite mean fidelity score was calculated for each clinician, by averaging their individual scores indicating use of the three key intervention resources with service users listed above, and providing a mean composite score ranging from 1 to 4. Summary statistics for fidelity to the intervention will be reported for the intervention group and individually for each cluster (team), by averaging the scores for all clinicians in each team who completed the questionnaire at each of the three time points.

The qualitative interviews

The EYE-2 qualitative interviews were conducted with reference to a topic guide, developed and informed by NPT and the logic models outlined in *Chapter 3*. The sEIP qualitative interviews were conducted with reference to standard EIP processes and policies and in light of emerging patterns in assessment and recruitment observed as part of the EYE-2 programme.

The EIP interview asked in both arms about numbers assessed and accepted onto caseloads, about the impact of AWTS, assessment processes, nature of clients taken on, changes in EIP service delivery and future needs for EIP.

The EYE-2 interview also asked about experience of training, understanding, implementation and appropriateness of the EYE-2 intervention and impacts of COVID, Brexit, and components of the logic model which was shared during the interview to prompt discussion of key local contextual issues.

Appendix 8 The Early Intervention in Psychosis qualitative data detailed summary

The EIP qualitative analysis was conducted from January to March 2020 and investigated from a multidisciplinary perspective further contextual factors specific to EIP service delivery, that may impact on the EYE-2 project intervention implementation and outcomes.

Two core and opposing themes emerged in relation to caseload management: Stringency in assessments versus Flexibility to take on uncertainty, and one additional theme focused on External Influences on Workload; while two themes focused on ways of working in EIP: Effective ways of working versus desire for change.

1. ***Increased stringency in assessments over time***: 10 teams described increased stringency in the assessment process over recent years. Some teams described that they had become better at conducting assessments with the aim of taking on fewer borderline cases. They felt they had grown in understanding of what FEP looked like and so accepted fewer people onto caseload. Others felt that acceptance had become more stringent with fewer borderline cases taken on due to service pressure and lack of resources.

   P06: *People with a personality disorder were taken on. We would get referrals from other teams and if you know [the] primary diagnosis [was] with a personality disorder. The way in which we work can be more detrimental to someone with that kind of diagnosis so I think people had a huge overload and now they are more backpedalling looking at their referral criteria and trying to be more stringent*.
   P10: *As a service we've kind of evolved and perhaps become a bit more erm a bit more better (sic) at identifying what is actually first episode psychosis and what, what is something else and might do better in a different treatment pathway*.
   P16: *I do wonder if our team has been a little bit stricter maybe about some of the younger people that, that maybe referred with, with hearing voices but not quite, you know, frequent enough to be taken on*.

Multiple factors were associated with this stringency. Three teams spoke directly of the link between the expansion of EIP services to include over 35-year-olds and fewer young people being taken on, 14 of the 20 teams referred to a more long-standing illness and complexity in those aged over 35, and 6 teams spoke of the impact on pressure and workload.

P16: *I suspect in our team sometimes if people have been really, really stretched and short staffed, I do wonder if some of the younger people may not have even progressed to the full face to face assessment, it might have been, you know, rejected at an earlier stage.*
P04: *The whole team's caseload is growing erm and it can be quite challenging because sometimes because it's with the over 35s, it's, sometimes that presentation has been quite longstanding.*
P03: *There is a relevance in terms of extra pressure on the service, so that was underestimated, the amount of referrals we have for the older age group . . . we haven't got corresponding staff for the extra so it was underestimated the probably about a quarter to a third more referrals due to the older age group.*

Three teams spoke of resources being an issue in taking on new cases.

P05: *I think we do try but having said that erm (name) I think you know I'm not saying that resources is a big factor in our thinking but erm I think there is an awareness that we have to be very careful with our resources.*

Seven teams said that AWTS had led to increased caseloads and referrals from other teams, and four mentioned that referral quality was poor, potentially as a result.

P06: *People refer to us quite quickly if they even sniff there might be a psychotic symptom even if it's just hearing voices as they know we need to see and assess and take on within 14 days. It takes the pressure off them.*

Three teams talked explicitly about reductions in flexibility and increases in gate-keeping.

P03: *So I would say we are still taking on people who are suitable probably not quite as erm you know as flexible as we might have been in the past with pressures of the service.*
P11: *I think services can spend too much time and energy in trying to find reasons not to offer a service and it is sometimes euphemistically called gatekeeping.*

But four teams described improvements in triaging and redirection to the best service.

P10*: So we've had a lot of it but maybe an increased amount of erm referrals from those places which may not be psychosis but may, may be other, you know, people needing some kind of mental health service, and people do know they get a good response from us, a quick response.*

2. **Flexibility to take on uncertainty:** Conversely at least four teams described being more flexible with accepting cases, with greater use of extended assessments when they were unsure whether a case was appropriate for their team. The theme revealed that some teams felt they were well-resourced and had the capacity to be flexible and take individuals onto caseload or extended assessments when there was some diagnostic uncertainty.

P18: *Really we are quite open in terms of assessment and interventions for people and our team is more likely to take people on where there's some diagnostic uncertainty you know because we are not sure where this is going.*
P01: *Maybe there's like more of a mood component and they'd be better suited to another team, but we don't have enough information off the first assessment. So generally we're quite flexible and we'll take them for like a more extended period of assessment.*

Ten teams said that the demand from over 35-year-olds didn't affect who they took on, although some teams said they had stopped working with over 35-year-olds.

P04: *Their age isn't . . . a hugely kind of contributing factor you know if they are presenting with symptoms of psychosis . . . and that is their primary diagnosis then they'll be open to our service.*
P18: *We've gone back to the original model of 14 to 35. We were accepting people over 35 for a 2-year pathway up until October last year but because that . . . it was due to service demand (sic).*

And 11 teams said that Access and Waiting Times did not influence who they took on but associated AWTS with waiting times and outcome measures.

P13: *Well access and waiting times doesn't have any impact on whether we take on a case or not.*

Four of these teams said they were person-centred and not focused on targets.

P18*: I think we try and sort of like really empathize about you know . . . what this person is experiencing and the impacts that's having on their life. I suppose as a team we're really keen to do that and try and put that person central to everything.*

3. **External influences on referrals and workload** were described that either led to reduced or increased demand.

Three teams mentioned reduced referrals due to a local ARMS or youth service.

P2: *The specific things are that we've got an arms caseload that people might not come onto the FEP caseload but will go onto ARMS.*

Three mentioned that families and young people not confident to seek help are sometimes not confident to seek help.

P16: *I sometimes wonder if that's to do with austerity and even whether the younger people give up earlier because they can't access the GP, they might give up at an earlier stage.*

And two talked about their service just not being very well-known.

> P09: *I still think that we are erm wither forgotten about or just not known about.*

Conversely, nine teams mentioned geographical impacts on increased referral rates in University towns and cities.

> P01*: Very crowded place, there's a lot of uh poverty, deprivation, racism, lack of job opportunities, drug use et cetera, so I think, yeah, there's just a lot more . . . evidence-based reasons why like [place] is . . . and living in a city as well, living in a [inaudible] urban area there's a reason why we, we take a lot more on, I think.*

Two teams mentioned that coworking with CAMHS led to longer and more complex assessments.

> P07: *I think we, you know, do try to be careful that we are taking people on that are clearly first episode psychosis and I think that does affect the CAMHS people because the, the young people tend to be more complex. Erm, and where there's sort of other things: trauma, dissociation, emerging personality, autism, things like that, it is quite tricky to try and work out what's going on.*

Six teams talked about inappropriate referrals and taking on inappropriate cases due to gaps in services elsewhere.

> P13*: We were noticing we had more people with an ASD diagnosis and is showing a gap in the service of mental health.*

While three teams talked about varying expertise of referrers

> P07: *I mean, I think it depends who's in CAMHS making referrals. That's one thing. Erm, and if you have clinicians that know about FEP or had training from us, erm it would just alert to those things.*

4. **Effective ways of working** – specific reference was made by at least one team to:

Outreach (leading to better-quality referrals)

> P10: *We have done a lot of kind of going out to people, going out to GP surgery's, going out to college's, going out to places where young people might be to try and educate our colleagues, in educating other health services about First Episode Psychosis.*

Treatment and discharge planning

> P20: *There's just a lot more thought really about the last 6 months and planning, erm, and trying not to sort of run over and, you know, kind of get another half a year, year, down the line before you discharge. So, so that might kind of free a little bit up.*

Employment specialists

> P08: *Well there has been some recent funding that has been accessed by the IPS service, the employment specialist, which has made a huge difference to the team.*

Good links with sports clubs, education providers, CAMHS, drug services etc.

> P12: *But I think in general terms we tend to get just as many referrals. We've also opened up to doing our own engagement with [education provider] and [university] so we have had a couple of extra referrals come through from them avenues really [sic].*

And having a dedicated, passionate team

> P18: *Everybody is so dedicated to making sure that we offer the best of what we do so I suppose that's maybe not about thinking about being a young team but maybe we probably . . . a fresh thinking . . . passionate team about you know the young people coming into our services and making sure they get the right service.*

While four teams mentioned being good at meeting AWTS

> P20: *I think the teams sort of adapted quite well really. So, there's, yeah, I think most of the time we've, well it feels like we meet it.*

5. **Desired change:** Finally teams highlighted changes that they would like to see which included

Increased funding and resources, mentioned by eight teams

> P13: *We used to have resources and time to go around to colleges and universities and youth clubs and those sorts of environments to talk about how to spot early intervention psychosis.*

Increase in staffing to match larger caseload mentioned by two teams

> P03: *I think there should be a recognition of the impact of having the older age range of people and you know more staff for that.*

Staff with a greater variety of skills mentioned by five teams

> P05: *We're working with a broader group and we need to be able to erm engage with all of them not just you know being good at engaging with young people which I think in the past we have been looking at specifically erm being able to engage with young people and trying to recruit people who have got experience in that or have got those skills.*

Increased awareness raising and outreach work mentioned by six teams

> P16: *An ideal world, we'd be a bit better staffed and be able more to reach out to like schools, colleges, doctors to advertise our service. That would help.*

Increased training by two teams

> P19*: It seems like we have new people in the team, needing more training.*

A cap on caseload by two teams

> P03*: I think you need very strict things around maximum caseload because there is no way of erm what's the word you know closing down referrals.*

And a more preventative focus and strategy by two teams

> P01*: Give talks, they try and they look after people that are kind of prodromal, try to stop people from, or if they had BLIPs and it's kind of working with people before they've had a psychotic episode?*

Summary from the EIP qualitative analysis

Interviews with all EIP/EYE-2 teams early in the intervention gave an indication of the context in which the EYE-2 intervention was delivered. A picture is shown of teams with commitment, pockets of good practice and visions for the future, facing challenges due to resources. The main contextual influence, in evidence across EIP teams, including

those delivering the EYE-2 intervention, was the significant service demands arising from a variety of factors, and the tendency for many teams towards more stringent assessment and acceptance processes, at least in part, to manage caseload size and complexity. This explains why substantially fewer young people were accepted onto caseload in teams at all but one site, than in previous years with in some cases only 8% of referrals being accepted as new FEP cases aged 14–35. Although not universal, the tendency to refuse those with psychosis symptoms in the context of personality disorder, mood disorder, and other diagnostic uncertainty means that those accepted onto EIP caseloads during the EYE-2 intervention were much more likely, than previously, to have a schizophrenia-spectrum diagnosis. Investments in EIP services over the last few years seem likely to have addressed some of the early resource issues, but reductions in working with diagnostic uncertainty likely remain.

Appendix 9 Implementation figures, tables, themes and quotes

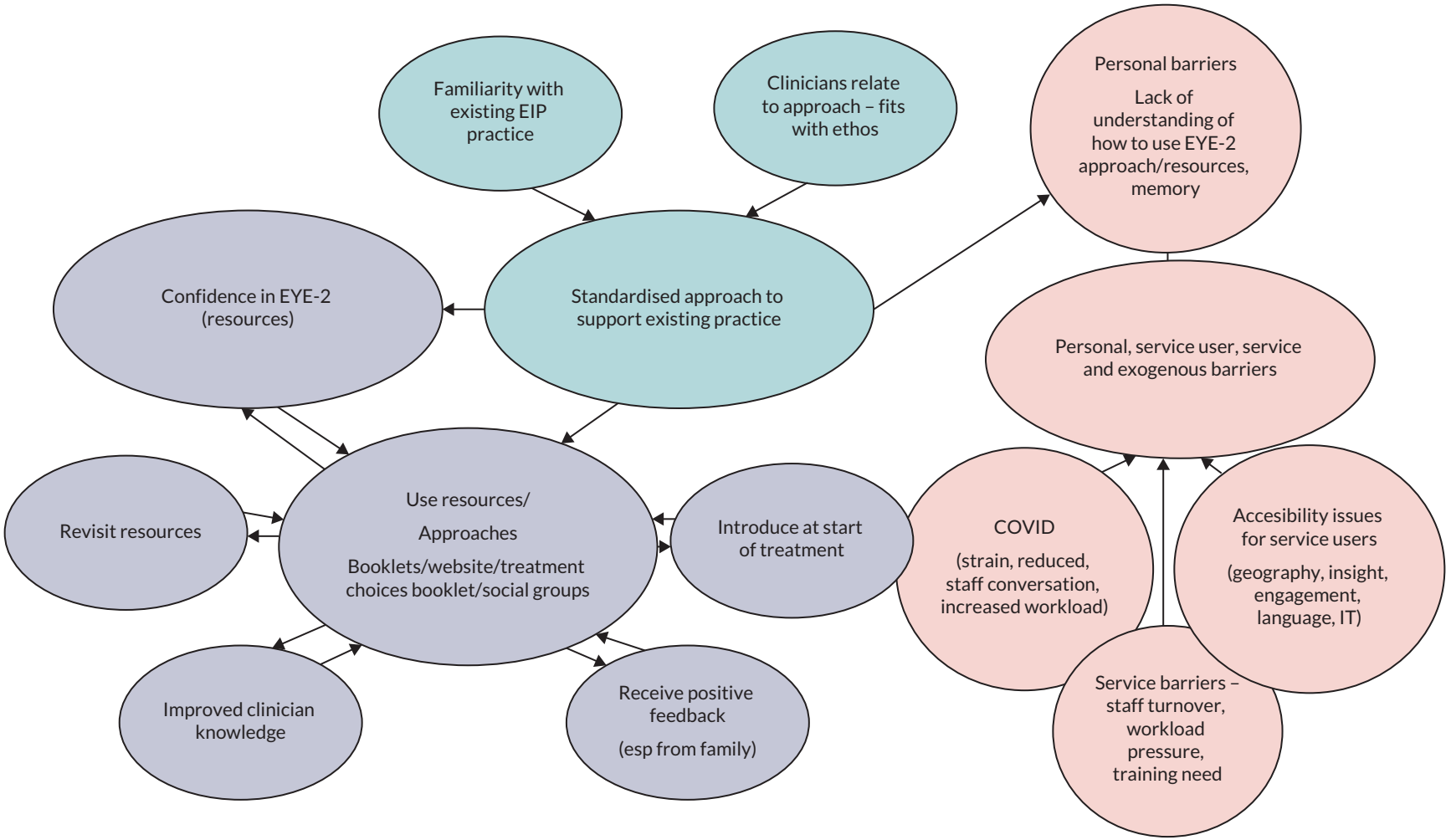

FIGURE 29 Initial themes involved in the early (round 1), middle (round 2) and late (round 3) stage of intervention delivery.

TABLE 45 Summary of facilitators to implementation

Themes		Team location																					
		London						Thames Valley				Hampshire				Norfolk				Manchester			
		Lambeth		Southwark		Lewisham		Oxford		Berkshire		N Hamps		E HAmps		Norwich		G Yarmo		Salford/N Man		Trafford	
	Round	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3
Facilitators	Received positive feedback about resources	■	■	■	■		■	■		■			■	■			■	■	■		■	■	■
	Familiarity with existing EIP practice	■			■					■	■	■	■	■		■	■					■	■
	Resources improve clinicians knowledge	■	■						■						■		■	■	■	■	■		■
	Staff conversations around EYE -2	■					■	■	■	■							■					■	
	Confidence in EYE-2		■		■				■									■		■	■	■	
	Standardised approach															■	■				■	■	
	Clinician relates to EYE-2 approach	■																			■	■	■

TABLE 46 Summary of barriers to implementation

Themes		Team location																					
		London						Thames Valley				Hampshire				Norfolk				Manchester			
		Lambeth		Southwark		Lewisham		Oxford		Berkshire		North Hampshire		East Hampshire		Norwich		Gt Yarmouth		Salford/N Manchester		Trafford	
	Round	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3
Barriers	COVID is a barrier	■	■		■			■	■	■	■	■	■	■	■	■	■	■	■		■	■	■
	Workload/ pressures	■		■				■	■		■	■	■	■	■		■	■	■	■	■	■	■
	Memory as a barrier	■	■		■			■		■		■	■	■		■	■			■		■	
	Benefit from more training		■	■	■			■	■	■	■		■		■				■	■	■		
	Accessibility for service-users		■				■	■	■		■	■			■	■					■	■	
	Lack of understanding of EYE-2		■	■	■						■		■					■	■	■			■
	EYE-2 not a priority			■			■			■					■			■	■			■	

TABLE 47 Normalisation process theory coding frame for phase 1 process evaluation

General construct	Specific construct	Example themes/subtheme from Claire's analysis	Summary of code underlined is all related to trust/confidence	What might be predicted next?
Coherence is the prospective sense-making work that people do individually and collectively when they are faced with the problem of operationalising EYE-2.	*Differentiation*: An important element of sense-making work is to understand how EYE-2 and prior practice are different from each other.	• Professional resources to represent EI – give good impression of service, something clients will like, better than other leaflets • Reliable and accessible information? – also later accessible resources – • Ways resources help clinicians (replaces printing and writing out info) – booklets help structure introduction • Resources for young people to reference • Areas of EYE_2 currently implemented (using EYE-2 resource as standard practice in initial meeting – promote and refer to social groups – use of MI) • Using resources with all EI caseload • Reminds/reassures/reinforces familiar approaches? • Ltd learning/change to practice? • EYE-2 Benefit – extra resources to use • EYE-2 Benefit – extra resource to run social groups – social group valued by clients • Learning and value aspects of EYE_2 – wider support context/MI/difft approach/client own goals • Using QPR/DIALOG • Regular EYE-2 training – initial and booster training useful	EYE-2 is different from prior practice because it provides extra resources to use and to run social groups It provides professional, accessible resources, that replace printed and written information, and can be used as a reference by young people. It allows professional to give something – to say go away and do this. Resources can be used as standard in initial meetings and with all caseload. EYE-2 also involved promoting and referring to EYE-2 social groups. Finally it reinforces familiar approaches such as use of MI approaches. There is also a focus on wider support context and client's own goals. EYE-2 involves using QPR/DIALOG and taking part in regular training.	People might forget to use over time? Website use may have increased? Might be used in place of contact? Increased conversations and use of booklets? Increased focus on wider support context?

continued

TABLE 47 Normalisation process theory coding frame for phase 1 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme from Claire's analysis	Summary of code underlined is all related to trust/confidence	What might be predicted next?
	Communal specification: Sense-making relies on people working together to build a shared understanding of the aims, objectives and expected benefits of EYE-2.	• Clinician/team-based discussions • Use of EYE-2 governed by how and who resources aimed at in training	Some teams have clinician and team discussions about EYE-2, but in part use of EYE-2 was governed by how and who resources were aimed at in training.	Clinician and team-based discussions > or <? How do people like you use this? How does it reflect the wider activity of the team?– Harder to pass on to new staff? Streamlined in terms of who is using? How has COVID influenced work reorganisation?
	Individual specification: Sense-making has an individual component too. Here participants in coherence work need to do things that will help them understand their specific tasks and responsibilities around EYE-2.	• Influences on use – familiarisation with the resources • Using resources supports further use – Exploring website as best way to learn to use website • Ways resources help clinicians – info to share/help introduce ideas/structure introduction • Use resources (in initial meeting) • Promote and refer into groups • Use MI approach	Individual actions to help understand individual tasks and responsibilities, include familiarisation with the resources and the website. Individual clinicians use resources in initial meetings, promote and refer into groups and MI approaches. Resources can help with information sharing, introducing new ideas, structuring introductions.	How familiar are clinicians with resources – website/booklets? More familiar = more use
	Internalisation: Sense-making involves people in work that is about understanding the value, benefits and importance of EYE-2.	• EYE-2 fits – • Philosophy and ethos of EI • Approaches and resources help with work • Relevant for service improvement • Resources as good/helpful ++ • Clinician and client view of resources ('encouraged to use materials as very good resource'; 'Feels clients are pleased to receive the resources' instil hope and recovery; helpful for families; peer quotes powerful and valuable; Ethnic diversity in resources useful for demographics of caseload; multiple languages on website as useful; resources have value with older people) • Reliable/accessible info	Values and benefits of EYE-2 are that the philosophy and those fit with EI, the approaches and resources help with work, and are relevant for service improvement. The resources are helpful and liked by clients, families, older people, and the information is reliable and accessible. The resources instil hope and recovery, and it is helpful that ethnic diversity and other languages are included in the website.	Extent to which structured into routine service use? Viewed as service or research?

TABLE 47 Normalisation process theory coding frame for phase 1 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme from Claire's analysis	Summary of code underlined is all related to trust/confidence	What might be predicted next?
Cognitive participation is the *relational work* that people do to build and sustain a community of practice around EYE-2.	*Initiation*: A core problem is whether or not key participants are working to drive EYE-2 forward.	• *Who uses EYE-2 – roles and characteristics – care co-ordinator/other roles* • Who uses EYE-2 CC use EYE-2 in role/care plan/OTs engage in social model, younger staff use more creatively	*The people working to drive EYE-2 forward are largely care co-ordinators in care planning, and OTs for social model. Younger staff drive forward as they work more creatively.*	*If younger staff drive use forward creatively – does this get lost as new staff come who aren't trained?* *Has there been greater organisation/planning about when to use what?*
		• Picking the right time – to use the resources – focus on client need – wait to use if unwell/high risk/crisis • *Hard to use if no acceptance of MH issues/service*	*A key issue is when to use, there may be a need to pick the right time, and not use if unwell, high risk or in crisis, or if no acceptance of mental health issues or service.*	
	Enrolment: Participants may need to organise or reorganise themselves and others in order to collectively contribute to the work involved in EYE-2.	• *Link to impact of role for example CC use due to care planning/OT engage more in social model of EYE-2* • *Using EYE_2 possible factors – who likely to implement – younger. IT literate, creative, adventurous, trained!*	*EYE-2 more likely to be implemented by care co-ordinators, OTs and those who are young, adventurous, creative, IT literate and trained.* *Need identified for further booster training/training for new staff* *Skill set workability/enrolment? Gives skills but explains why should be part of something? Common to ask for more training – as know it departs from intervention given*	*Who is most likely to use the approach in your team?* *What most influences use – caseload vs. support encouragement from colleagues/others?*
	Legitimation: An important component of relational work around EYE-2 is the work of ensuring that other participants believe it is right for them to be involved, and that they can make a valid contribution to it.	• *Influences on use – New staff enthusiasm sparks interest* • *Positive feedback from staff and service users* • *Positive appraisal by clinician of resources* • *Influences on client/family/carer use (as considered by the clinician)* • Finding resources useful with families works as a prompt to use • *Reminds, reassures and reinforces familiar approaches and skills already taught*	*Other people think it's right for someone to be involved, in that there has been positive feedback by staff and service users, positive appraisals of the resources by clinicians. The resources have been valuable for use with families, which encourages more use, as well as for clients, and new staff enthusiasm sparks interest further.*	*What most influences you to use EYE-2* *Relational for example, staff/SU enthusiasm/feedback vs. own experience of value?*

continued

TABLE 47 Normalisation process theory coding frame for phase 1 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme from Claire's analysis	Summary of code underlined is all related to trust/ confidence	What might be predicted next?
	Activation: Once it is underway, participants need to collectively define the actions and procedures needed to sustain EYE-2 and to stay involved.	• *Using EYE-2 resources in initial meeting – standard practice* • *Promote and refer into social groups* • *Using MI* • *(Does picking the right time to use resources fit here?)* • *Need EYE-2 training – want booster training; training for new staff*	*Actions and procedures need to sustain EYE-2 include using resources from initial assessment as standard practice, using MI and promoting and referring to social groups. This includes also picking the right time to use the resources. A need was identified for further booster training and training for new staff.*	*What is core from EYE-2?* *When is it best to use each EYE-2 approach?*
Collective action is the operational work that people do to enact EYE-2.	*Interactional workability*: This refers to the interactional work that people do with each other, and with the components of EYE-2 when they seek to operationalise them in everyday settings.	• EYE02 and new staff – introduce resources to Staff/new staff need EYE-2 training • Clinicians discuss EYE-2 with EYE-2 RA • Useful for clinician/team/in supervision discuss EYE-2 approach and resources • Need staff/team to discuss EYE-2/share information/examples and review website [here or in communal appraisal?_ • Make resources accessible – EYE-2 link as bookmark on phone, team i-pads for EYE-2 resources, Likemind cards in bag, resources in car as prompt [here or in individual readiness] • Using resources supports further use – using resources day to day helps to use	Interactional work with each other to operationalise EYE-2 in EIP includes, staff introducing resources to new staff, staff discussing EYE-2 with the RA, in team meetings and in supervision. Needs were identified for new staff training, and for sharing of information and examples, and reviewing the website. In terms of interaction with components of the intervention, staff described making the resources accessible through a range of electronic and physical prompts and reminders, as well as through daily practiced use to enhance familiarity.	How is the ethos of EYE-2 kept alive in COVID? What do you do WITH SU that's IT related as opposed to given to? Is there shared discussion in EIP regarding how to use booklets? How often discussed in supervision?
	Relational integration: This refers to the knowledge work that people do to build accountability and maintain confidence in EYE-2 and in each other as they use them.		Almost all constructs interact with trust and confidence/knowledge The resources are helpful and liked by clients, families, older people, and the information is reliable and accessible.	How has trust/confidence in EYE-2 changed over time? Know when to use EYE-2? Issues if SU has limited language/cogn skills?
	Skill set workability: This refers to the allocation and training work that underpins and is built up around EYE-2 as it is operationalised in the real world.	• EYE-2 and new staff – introduce resources to staff/new staff need EYE-2 training • Initial training and booster training as useful • Need reminders about using the website	In terms of allocation and training, some staff described introducing new staff to the resources. However, it was also mentioned that while initial training and booster had been useful, new staff still needed training, and staff needed more reminders to use the website. *A need was identified for further booster training and training for new staff.*	

TABLE 47 Normalisation process theory coding frame for phase 1 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme from Claire's analysis	Summary of code underlined is all related to trust/confidence	What might be predicted next?
	Contextual integration: This refers to the resource work – supporting EYE-2 through the allocation of different kinds of resources and the execution of protocols, policies and procedures.	• Areas of EYE_2 currently implemented (using EYE-2 resource as standard practice in initial meeting – promote and refer to social groups – use of MI) • Using resources with all Ei caseload • Risk-related comments – in a crisis might use approach/reinforce website in care plan • EYE-2 reminder, posters and staff guides (action list) help to use EYE-2 resources/approaches	The delivery of EYE-2 is supported through new protocols and procedures including using EYE-2 resources as standard practice in initial meetings, for all EIP caseload. Also supporting delivery, the website can be used in a crisis as part of a care plan; promotion and referral can occur to social groups, and staff can be supported to use EYE-2 approaches though reminders, posters and staff guides (checklists) of resources and approaches.	
Reflexive monitoring is the retrospective *appraisal work* that people do to assess and understand the ways that EYE-2 affects them and others around them.	*Systematisation*: participants in EYE-2 may seek to determine how effective and useful it is for them and for others, and this involves the work of collecting structured information in a variety of ways.		*? not sure I saw anything here.*	
	Communal appraisal: participants work together – sometimes in formal collaboratives, sometimes in informal groups to evaluate the worth of EYE-2. They may use many different means to do this drawing on a variety of experiential and systematised information.	• Useful for clinician/team/in supervision discuss EYE-2 approach and resources • Staff attitude/view – All invested in EYE-2 – pleased to be randomly picked to use materials • Staff attitude/view – Team feels a bit distant from EYE-2 • Staff attitude/view – At first negative view of EYE-2 as something else to try	Communal informal appraisal included a general consensus that it would be useful for clinicians and teams to discuss EYE-2 in supervision. Some staff described how all staff were invested in EYE-2 and pleased to be taking part, while others felt EYE-2 started off negatively as something else to try, and others felt it is now a bit distant from EYE-2/.	

continued

TABLE 47 Normalisation process theory coding frame for phase 1 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme from Claire's analysis	Summary of code underlined is all related to trust/confidence	What might be predicted next?
	Individual appraisal: Participants in a EYE-2 also work experientially as individuals to appraise its effects on them and the contexts in which they are set. From this work stem actions through which individuals express their personal relationships to new technologies or complex interventions.	◦ Peer quotes powerful and valuable; feedback from service users ('Client was positive about website'). ◦ Finding resources useful with families works as a prompt to use ◦ View of social groups – we need social groups/EYE-2 social groups appeal to people/clients look forward to them/easy to refer	In terms of clinicians' individual appraisals of the effects of EYE-2 on themselves and their context, people talked about positive peer, service users and family feedback being powerful and observation of positive effects on families encouraging further use. Some talked about social groups being needed, appealing to people, and clients looking forward to them.	
		◦ Offer resources but clients won't use (or clinicians presume they are not being read) ◦ Use of booklets limited to distribution only – recognition that should start using them in work with clients	Others talked of their beliefs that clients wouldn't use resources, or of their own recognition that they only gave out booklets, and they really need to use them with their clients.	
		• EYE-2 distant/less enthusiasm with time • Memory as a barrier • *Reminds, reassures and reinforces familiar approaches and skills already taught* • Learning and valuing aspects of EYE-2 approach (wider support context, MI, using a different approach, client own goals) • EYE-2 initial training and booster as useful	Some talked about the initial and booster training as useful, to learn MI, and alternative approaches, draw on the wider support context and focus on the clients own goals and as a reminder and reinforcement of familiar approaches and skills. Others talked about memory acting as a barrier to delivery, or that enthusiasm had waned as EYE-2 had felt more distant.	
	Reconfiguration: appraisal work by individuals or groups may lead to attempts to redefine procedures or modify EYE-2.	• *Requests for translated material – English version of languages choices on website.* • *Clinician wants general MH info on website.* • *Views/feedback on social groups – Social group with drop-in approach might work better.*	*There were a few mentions of reconfiguration, attempts or preferences for redefining EYE-2 approaches. People valued the translated materials and alternative languages for the website, but one clinician wanted general mental health information on the website, and another thought social groups would work better as drop ins.*	
Features of EYE-2	*Plasticity*: The extent to which EYE-2 components are malleable and can be moulded to fit their contexts.		? translation of materials	

TABLE 47 Normalisation process theory coding frame for phase 1 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme from Claire's analysis	Summary of code underlined is all related to trust/ confidence	What might be predicted next?
	Elasticity: The extent to which contexts can be stretched or compressed in ways that make space for EYE-2 components and allow them to fit.		? nor here	How has EYE-2 changed how people interact with service users? What experience of confidence/ burden?
	Coupling: Relations of dependence between people, EYE-2 components, and the contexts in which they are working.	• Reading and language skills limit service user's ability to use resources • Barriers to using website – lack of access to technology (clinicians and service users), low technology skills of staff • Barriers to social groups – older people take up social groups more • Social group staff had difficulties engaging service users and planning group with team • EYE-2 staff member a visual prompt/reminder to use EYE-2	In terms of dependence between people, components and context, reading and language skills, and lack of access to technology limit service user engagement with materials. Staff also struggled if they had limited access to technology or low skills to use the website. Some said social groups were preferred by older clients, and others said EYE-2 staff had struggled to plan groups with the team, to engage service users. EYE-2 staff served as a helpful visual prompt to use the approach/	
Negotiated outcomes	*Normative restructuring*: Changes to professional norms, rules and resources as a result of working with EYE-2.	• EYE-2 benefit – extra resources to use • Recognition that should be using booklets in work with clients	In terms of changes to professional norms, rules and resources, EYE-2 was seen as an extra resource (both booklets and social groups); some teams mentioned that they should be using the resources more in their work with clients	
	Relational restructuring: Changes to the ways that people are organised and relate to each other as a result of working with EYE-2.	• Social groups can now be run because of extra EYE-2 resources	In terms of changes to the ways that people relate to each other, some clinicians said that social groups could now be run because of the extra EYE-2 resource	
Readiness and commitment	*Individual readiness*: Participants' readiness to translate individual beliefs and attitudes about EYE-2 into behaviours that are congruent, or not congruent, with (new) system norms and roles.	• EYE-2 distant – less enthusiasm – EYE-2 forgotten – contributed to if lack of feedback or engagement not an issue • Lack of memory of website name • Don't feel familiar with resource content to use • Not started using anything properly • Perceived negative impact – resources limit detailed discussion, and may raise unreasonable expectations re access to treatments	Readiness to translate beliefs into EYE 2 congruent norms and roles seemed more linked to needing or having reminders, including reassurance and reinforcement for familiar approaches, and a reflection that these principles should be used, and using the resources with all EI caseload. (possibly need more from above in here?)	

continued

TABLE 47 Normalisation process theory coding frame for phase 1 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme from Claire's analysis	Summary of code underlined is all related to trust/confidence	What might be predicted next?
		• Need reminders to use website • Interview itself as a reminder to use website will write website name on booklet • Reminds, reassures and reinforces familiar approaches – reflection on previous work and that these principles should be used • Using resources with all EI caseload – regardless of age	Some talked about barriers/lack of readiness whereby EYE-2 felt distant, forgotten, and met with less enthusiasm. Some people described not feeling familiar enough with content to use it, forgetting the website name, and having concerns that resources might limit discussions, or raise unreasonable treatment expectations.	
	Shared commitments: Participants' readiness to translate shared beliefs and attitudes about EYE-2 into behaviours that are congruent, or not congruent, with (new) system norms and roles.	• Barriers assoc with service demands – specifically new staff – makes EYE feel more distant – new staff not in initial training • Barriers to access social groups – low resources to get clients to social groups • Feel there is more team could be doing to implement EYE-2 • Staff attitude (commitment) -all invested in EYE-2 – everyone pleased to be randomly picked to use materials	In terms of the potential for translating shared beliefs into action, some teams talked about the commitment, with all staff being invested in EYE-2 and pleased to have been picked to receive the materials. Other teams felt that there was more the team could do to implement EYE-2, that the arrival of new staff (rather than inspiring new enthusiasm) meant EYE-2 felt more distant, especially as new staff were not trained, and the team had limited resources to get someone to a social group, for example.	
Process limiting factors	*External (exogenous) processes* and events that shape the capacity of participants to implement and operationalise EYE-2 (e.g. Austerity, COVID)	• Social groups stopped running due to start of COVID-19.	Only one notable exogenous process affected implementation and this was a mention in a late transcript of COVID-19 stopping social groups from running.	
	Internal (endogenous) processes and events that shape the capacity of participants to implement and operationalise EYE-2 (e.g. staff shortages, strategic initiatives)	• Barriers associated with service demands and pressures – time/low staffing/service demands (caseload – paperwork – risk management – duty work) • Reading and language skills of the service users (sometimes too limited to use resources) • Memory as a barrier (forget to use EYE-2/website) • Lack of access to technology/low technology skills/memory of website name	In terms of endogenous processes that shape capacity to implement EYE-2, these include service demands and pressures such as low staffing, limited time, caseload, paper work, as well as lack of access to technology. They also mentioned their own memory as a barrier, and service users reading and language skills.	Adapting because SU has low reading and language skills links to relational aspects of care

TABLE 48 Normalisation process theory coding frame for phase 2 process evaluation

General construct	Specific construct	Example themes/subtheme	Summary of code
Coherence is the prospective sense-making work that people do individually and collectively when they are faced with the problem of operationalising EYE-2.	*Differentiation*: An important element of sense-making work is to understand how EYE-2 and prior practice are different from each other.	• Good-quality booklets and website – gave confidence in EIP. • Booklets improve service users understanding – accessible information. • Beneficial to have resources focusing on just psychosis. • Social groups valuable. • Resources for young people to reference. • EYE-2 provides a standardised approach. • Completing QPR/DIALOG – easier to use than previous versions. • EYE-2 training – initial and booster training useful. • Uses cards to give clients information on Likemind website. • Resources help to engage and focus on areas that may have otherwise been missed. • Promoting resources – handing out booklets in meetings, revisiting with service users, giving info on Likemind, referring to social groups. • Provides service users independence in their treatment. • Motivational techniques have been helpful. • EYE-2 does not offer anything different.	*Clinicians identified that the booklets give accessible information about psychosis to the service users to improve their understanding.* *The clinicians also stated that the booklets seemed of high quality which may have improved service and families' confidence in the EIP services.* *The resources provide service users with independence as they are able to use the resources in their own time.* *Learning motivational techniques is a key difference as some clinicians had very little or no training on this previously.* *However, some clinicians were unable to see how the EYE-2 differed from previous practice.*
	Communal specification: Sense-making relies on people working together to build a shared understanding of the aims, objectives and expected benefits of EYE-2.	• Learning through staff discussions. • Limited staff discussions due to remote working. • Lack of understanding of the EYE-2. • Teaching new staff about EYE-2. • Beneficial to see other staff implementing the EYE-2 – encourages other team members to utilise resources.	*Clinicians mentioned the value of learning through informal staff discussions in the office. Some teams found that staff discussions around the EYE-2 were limited due to remote working. Clinicians also mentioned teaching new staff about EYE-2.*
	Individual specification: Sense-making has an individual component too. Here participants in coherence work need to do things that will help them understand their specific tasks and responsibilities around EYE-2.	• Using booklets to introduce EYE-2. • Booklets improve clinicians own understanding. • Revisiting the website is beneficial for clinicians. • Using resources in initial meetings. • Promoting social groups. • Uses MI with service users.	*The clinicians identified that looking through the website and booklet resources helped them learn and also helped them frame introductions with new service users.*

continued

TABLE 48 Normalisation process theory coding frame for phase 2 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
	Internalisation: Sense-making involves people in work that is about understanding the value, benefits and importance of EYE-2.	• EYE-2 mirrors EIP ethos. • Provides a standardised approach. • EYE-2 has fit in well with general practice. • EYE-2 has enhanced the service. • Good resources for staff to learn from. • Clinicians relate to the EYE-2 approaches and resources. • Positive feedback from staff, service users and families. • Provides positive resources about psychosis. • Reliable/accessible info. • Positivity regarding the range of languages the resources are offered in.	The EYE-2 mirrors the ethos and values of EIP. The EYE-2 provides a standardised approach so that all staff are working the same. Values and benefits of EYE-2 are it fits well in standard EIP practice and provides resources for staff to learn from. A few clinicians also identified the value of having resources accessible in multiple languages as they often work with diverse populations.
Cognitive participation is the *relational work* that people do to build and sustain a community of practice around EYE-2	*Initiation*: A core problem is whether or not key participants are working to drive EYE-2 forward.	• Who uses EYE-2 – care-cos and nurses use more, younger staff better at remembering to use, support workers may be less aware. 'old-school colleagues don't find them helpful'. • Picking the right time – unlikely to use on service users who are challenging to engage/*no acceptance of MH issues – waiting for the right time to use.* • *Challenging to engage people over the phone to complete QPR* and *Dialogue.* • *Resources not suitable for everyone – lack capacity.* • *Not promoting it initially as it can be overwhelming.* • *Accessing resources in remote working – unable to stock resources at home.* • *COVID-19 – unable to attend social groups.* • *Treatment choice booklet is too thick.*	*The staff driving the EYE-2 forward seem to be the care-cos and nurse, whereas support workers may be less aware of EYE-2 and therefore less likely to use it.* *A key issue was that clinicians are unlikely to use resources when clients lack insight or capacity, are challenging to engage or are unaccepting of their diagnosis. Clinicians waited for the right time, resources less helpful if lacking capacity, or initially when info may be overwhelming, unable to stock resources at home when home-working.* *Another issue is COVID-19 causing social groups to move online. Some clinicians suggested that Zoom social groups were too intrusive and had poor attendance.* *Clinicians also found that the treatment choices booklet can be off putting as it has a lot of information to go through.*
	Enrolment: Participants may need to organise or reorganise themselves and others in order to collectively contribute to the work involved in EYE-2.	• *Care-co's incorporate the resources into care planning.* • *Incorporating the booklets and website into standard practice rather than just handing them out.*	*Clinicians have used the booklet and website resources when creating care plans.* *The also reorganised their practice to incorporate the booklets in sessions with clients rather than just handing them out.*
	Legitimation: An important component of relational work around EYE-2 is the work of ensuring that other participants believe it is right for them to be involved, and that they can make a valid contribution to it.	• *Confidence in EYE-2 approach and resources.* • *Positive feedback from staff, service users, carers and families.* • *Positive feedback promotes further use of resources.* • *The booklets were good resources for carers through COVID-19.* • *Reminds, reassures and reinforces familiar approaches and skills already taught.*	*Clinicians had trust and confidence in the EYE-2 approach and resources which promoted use. They also received positive feedback which encouraged clinicians to use the resources more with service users. The clinicians also liked the familiarity of the EYE-2 as it is similar to the EIP ethos.*

TABLE 48 Normalisation process theory coding frame for phase 2 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
	Activation: Once it is underway, participants need to collectively define the actions and procedures needed to sustain EYE-2 and to stay involved.	• *Using EYE-2 resources in initial meeting – standard practice.* • *Promote and refer into social groups.* • *Need more training – new staff haven't received training, need reminders of how to use EYE-2.* • *Gives resources to clients and families, revisits the resources.* • *Posting booklets during lockdown.* • *Promoting website and social group.* • *Using resources to review care plans.* • *Carrying QPR and Dialogue pad in bag/boot of car* • *E-mailing online copies of booklets to service users.*	*Actions to sustain using the EYE-2 were using them with all caseloads in initial meetings and promoting resources. The clinicians identified a need to increase training as new staff and existing staff need refreshers on how to use the EYE-2 in practice. Clinicians also started posting booklets and emailing online copies of booklets to service users when necessarily through lockdown. Some clinicians had a stock of the QPR and dialogue resources in their car to ensure they always had them to hand.*
Collective action is the operational work that people do to enact EYE-2.	*Interactional workability*: This refers to the interactional work that people do with each other, and with the components of EYE-2 when they seek to operationalise them in everyday settings.	• Accessing resources – carrying booklets in bag, keeping QPR and dialogues in car, picking up resources from main hospital. • Training new staff – directing new staff to Ras, giving resources to new staff, sharing information with new staff. Including EYE-2 info in information packs. • Staff discussion – speaking about particular service users in relation to EYE-2, speaking about EYE-2 in supervision. • Using EYE-2 resources in progress notes.	Staff operationalised the resources into daily work by keeping them accessible. Some of the teams have integrated EYE-2 information into their induction packs so they are introduced to the EYE-2 early on.
	Relational integration: This refers to the knowledge work that people do to build accountability and maintain confidence in EYE-2 and in each other as they use them.	• Discussing use of EYE-2 in staff meetings • Asking clients for feedback	Clinicians identified the benefit of mentioning the EYE-2 in staff meetings. One clinician identified how their team explored using the resources and approaches with a challenging service user.
	Skill set workability: This refers to the allocation and training work that underpins and is built up around EYE-2 as it is operationalised in the real world.	• EYE-2 and new staff – referring new staff to booklet resource, advise new staff about the website. • Need more MI training. • Initial training and booster training as useful. • Need reminders about using the website and booklets. • Lack of training for new staff. • MI training lacked depth.	A need for more training on MI was addressed by a couple of the clinicians as they felt it wasn't being used as they lacked confidence.
	Contextual integration: This refers to the resource work – supporting EYE-2 through the allocation of different kinds of resources and the execution of protocols, policies and procedures.	• Visual prompts, EYE-2 posters in office and reception, booklets in bookshelf. • Using booklet and website to care plan. • Can't find a home for booklets. • Designated staff member to order stock of resources – QPR pads, booklets. • Areas of EYE_2 currently implemented (using EYE-2 resource as standard practice in initial meeting – promote and refer to social groups – use of MI).	Some of the teams integrated the EYE-2 by making a visual presence of resources within the office. The clinicians whom did this noted that it was beneficial for remembering to use the EYE-2 resources. However, some teams struggled to find a home for the resources.

continued

TABLE 48 Normalisation process theory coding frame for phase 2 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
Reflexive monitoring is the retrospective *appraisal work* that people do to assess and understand the ways that EYE-2 affects them and others around them.	*Systematisation*: participants in EYE-2 may seek to determine how effective and useful it is for them and for others, and this involves the work of collecting structured information in a variety of ways.	• *EYE-2 lacks value?* • *Mixed feedback from service users*	
	Communal appraisal: participants work together – sometimes in formal collaboratives, sometimes in informal groups to evaluate the worth of EYE-2. They may use many different means to do this drawing on a variety of experiential and systematised information.	• Found it useful to discuss EYE-2 in meetings – presence of EYE-2 RA was helpful to keep it as a topic of conversation. • Staff attitude/view – team feels a bit distant from EYE-2/unaware. Not a priority. • *Some staff are unaware of the EYE-2* • *Clinicians were initially resistant to EYE-2* • *Consensus in the team that the EYE-2 offers nothing new.*	Some clinicians found that the EYE-2 hadn't been integrated well within their team and suggested that the EYE-2 felt very separate from standard practices. Some clinicians noted that members of their team were unaware of the EYE-2.
	Individual appraisal: Participants in a EYE-2 also work experientially as individuals to appraise its effects on them and the contexts in which they are set. From this work stem actions through which individuals express their personal relationships to new technologies or complex interventions.	◦ Positive feedback from staff, service users, families and carers. ◦ Positive feedback promotes use. ◦ Stopped offering the social group because of low uptake. ◦ Offer resources but clients won't use – clients ignore, put resources in the bin or use them as paper weights. ◦ Use of booklets limited to distribution only – recognition that should start using them in work with clients. ◦ Positive feedback about social groups. ◦ Initially the Likemind website felt as if it was missing information. ◦ QPR and dialogues useful when lost with a service user. ◦ Feels unnatural to use resources – communication is better when its working knowledge. ◦ EYE-2 slots into the visits. ◦ Treatment choice booklet useful – favourite resource. ◦ EYE-2 offered no benefits to me as a clinician. ◦ EYE-2 distant/not a priority (COVID-19). ◦ Less use of resources during lockdown. ◦ Memory as a barrier. ◦ EYE-2 initial training and booster as useful. ◦ EYE-2 is not anything new. ◦ COVID-19 is not a barrier – EYE-2 has helped save time during COVID as it provides structure – doesn't get in the way of normal practice – doesn't add to workload.	Clinicians received positive feedback regarding the EYE-2 resources which promoted further use with their caseload. However, when the social group received low uptake, two clinicians noted that they stopped offering it to patients. The treatment choices booklet received positive praise from a majority of clinicians and suggested it was the most useful out of the resources. Some clinicians stated that EYE-2 was not a priority during COVID-19 – some noted that they were struggling to complete the tasks they had to do during this time. However, a couple of clinicians suggested that COVID-19 was not a barrier to implementation as the EYE-2 doesn't demand much of your time but a little reconfiguration of how they usually do things to integrate the resources in to practice. A few clinicians felt that this actually saved time as they could leave patients to go through treatment choices independently rather than spending time explaining. They felt this was a better and more appropriate use of their time.

TABLE 48 Normalisation process theory coding frame for phase 2 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
	Reconfiguration: appraisal work by individuals or groups may lead to attempts to redefine procedures or modify EYE-2.	• *Developing an App for EYE-2 could be beneficial.* • *Uses resources with all age clients.* • *Picture resources could be beneficial.* • *More training/refreshers.* • *Online Self-help portal.* • *Online workbook resources.*	*Many of the clinicians highlighted that often their caseload was not appropriate for the EYE-2 as their service users were not in the correct age range. Some clinicians opted to use the resources with these service users anyway and suggest that it would be beneficial to make the resources accessible for all ages.* *One clinician noted that picture resources could be helpful when service users lack capacity.*
Features of EYE-2	*Plasticity*: The extent to which EYE-2 components are malleable and can be moulded to fit their contexts.	• Clients can dip into resources as their own pace. • Booklets not suited to online sessions.	Clinicians found it useful that clients could dip in and out of resources at their own pace and refer back to them. Also expressing the benefit of being able to choose what resources to use based on where the service user is in their recovery.
	Elasticity: The extent to which contexts can be stretched or compressed in ways that make space for EYE-2 components and allow them to fit.	• Materials and approaches slot in with routine visits?	
	Coupling: Relations of dependence between people, EYE-2 components, and the contexts in which they are working.	• Barriers to using website – lack of access to appropriate technology (clinicians and service users), low technology skills of staff, lack of data to use website, poor staff phone technology • Barriers to social groups – low uptake on virtual social group, too invasive, when in person the location of social groups can be inaccessible • Service users being above the age range for the intervention	Accessibility of resources posed as a barrier for implementation as some service users do not have the appropriate technology such as WIFI/4G, iPads etc to use the resources effectively. Accessibility issues with location of some social groups may have caused low uptake.
Negotiated outcomes	*Normative restructuring*: Changes to professional norms, rules and resources as a result of working with EYE-2. *Relational restructuring*: Changes to the ways that people are organised and relate to each other as a result of working with EYE-2.	• EYE-2 benefit – extra resources to use. • Staff inductions for EYE-2 have become more formal as staff discussions have decreased due to COVID-19.	

continued

TABLE 48 Normalisation process theory coding frame for phase 2 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
Readiness and commitment	*Individual readiness*: Participants' readiness to translate individual beliefs and attitudes about EYE-2 into behaviours that are congruent, or not congruent, with (new) system norms and roles.	• Unable to go through resources because of workload/ pressure. • Forgets that the EYE-2 is running. • Lack of memory of website name – easier to remember to recommend sites they have been using for years. • Recognitions that they should use resources more. • Not started using anything properly – hasn't used booklets, website or promoted social groups with clients. • Unaware of MI techniques – need more training to feel confident. • Perceived negative impact – makes conversation too structured. • AP reminders – need reminders to use website, booklets and to complete QPR and Dialogues. • Similarity and familiarity with existing practices – provides reassurance that they are already doing their job within the EYE-2 principles. • Using resources with all EI caseload – regardless of age – some clinicians only have a couple of patients in their caseload that are within the age range.	Some clinicians expressed that they would like to use the resources but due to workload and pressures they were unable to. Memory also posed as a barrier of implementation as clinicians have many things to consider within daily tasks that the EYE-2 is not at the forefront of their mind. Many of the clinicians noted that the RA reminders were useful to remind them to revisit and utilise all of the EYE-2 resources. Clinicians noted that they felt reassured that they were doing their jobs well because of how familiar the EYE-2 was to their standard practice. Some noted that the only difference was the inclusion of resources.
	Shared commitments: Participants' readiness to translate shared beliefs and attitudes about EYE-2 into behaviours that are congruent, or not congruent, with (new) system norms and roles.	• Barriers to access social groups – low resources to get clients to social groups. • Care-co's picking up clients so that they can attend social groups. • Feel there is more team could be doing to implement EYE-2 – more staff discussions around EYE-2 – more promotion of resources – especially social groups. • Staff attitude (commitment) – all invested in EYE-2 – happy to be part of the study – worried that they resources will go away after the trial ends. • Everyone puts engagement at the forefront of their mind. • The team is good at using the EYE-2. • Unsure how others use EYE-2 – doesn't spend a lot of time in the office. • Different staff member use the resources differently – use with clients, give as an independent resource.	Overall clinicians expressed positive attitudes towards being part of the study as the resources have been beneficial to patients, families and clinicians. The EYE-2 reminds staff to keep engagement on the forefront of their minds when interacting with patients – especially those that are new to the caseload. Clinicians also noted that they ways in which they use the resources vary between clinicians within each site and depending on the patients. Using their own skills to determine when is best to introduce the resources and whether to go through the resources with the patient or ask them to use them independently.

TABLE 48 Normalisation process theory coding frame for phase 2 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
Process limiting factors	*External (exogenous) processes* and events that shape the capacity of participants to implement and operationalise EYE-2 (e.g. Austerity, COVID)	• COVID-19 has change everything – EYE-2 not a priority. • Lack of uptake in online social groups • Remote working – issues accessing resources.	COVID-19 seemed to be a barrier to implementation as clinicians had to change the way that they worked with less F2F contact and higher pressures. The social group uptake seemed to really diminish at this point.
	Internal (endogenous) processes and events that shape the capacity of participants to implement and operationalise EYE-2 (e.g. staff shortages, strategic initiatives)	• High workload is a barrier to implementation (increased due to COVID-19, caseload, demands). • Staff shortages (maternity leave, shielding due to COVID-19) – Brexit. • New staff – lack of EYE-2 training. • Memory as a barrier (clinicians forget to use EYE-2/ website). • Lack of access – resource location.	Staff shortages and staff turnover was highlighted by clinicians. One clinician noted that none of the staff from when initial EYE-2 training was conducted were still there.

TABLE 49 Normalisation process theory coding frame for phase 3 process evaluation

General construct	Specific construct	Example themes/subtheme	Summary of code
Coherence is the prospective sense-making work that people do individually and collectively when they are faced with the problem of operationalising EYE-2.	*Differentiation*: An important element of sense-making work is to understand how EYE-2 and prior practice are different from each other.	• Good quality resources which help to improve confidence and trust in EIP. • Booklets provide a psychoeducational approach and challenge clients stigmas on psychosis. • Social groups are really valuable. • EYE-2 provides a standardised approach for the whole team to work within. • Easy to read and accessible information in booklets. • Social group has been beneficial for patients – able to support each other and make friends in similar situations. • Training useful – updating and consolidates information on MI • Booklet resources helps clinician structure sessions and stay on track – helps saves time. • Written resources help clinicians improve their own understanding. • Provides standardised approach.	*Clinicians noted the value of having 'professional looking resources', suggesting that this built patients confidence about what the clinicians were saying and offering. Also suggesting that the booklet resources were particularly beneficial as sessions can be overwhelming so it gives them something they can revisit at a later date.* *The EYE-2 differs from previous practice as it provides a standardised approach for all clinicians to work from even though the EYE-2 is familiar to what they are already implementing.*
	Communal specification: Sense-making relies on people working together to build a shared understanding of the aims, objectives, and expected benefits of EYE-2.	• Staff discussions are less frequent and more structured since COVID-19 – less able to learn and share experiences of using the EYE-2. • Lack of understanding of EYE-2 – staff haven't attended training or have forgotten what they learnt in training as they attended EYE-2 training years ago. • Teaching new staff about EYE-2 – EYE-2 resources and info is now part of staff induction pack.	*Clinicians noted that staff discussions have changed since COVID-19, they have become very formal and structured so has been challenging to have conversations regarding the EYE-2. Some clinicians believe that these conversations would have come up naturally in conversation if they were all working in the office.* *Clinicians also noted confusion or lack of understanding around EYE-2 as not all staff had received training or it was years ago so they didn't feel confident sharing information about EYE-2 with other staff or service users.* *However, some teams had implemented using the EYE-2 resources into new starters induction packs so they were aware of EYE-2 before receiving training.*
	Individual specification: Sense-making has an individual component too. Here participants in coherence work need to do things that will help them understand their specific tasks and responsibilities around EYE-2.	• Using booklets at the start of treatment – revisiting different booklets based on where the patient is in their recovery journey. • Promoting the use of the social group – referring new patients – revisiting going to social groups with patients who may have initially been apprehensive.	Clinicians identified the benefit of having the booklets aid them at each different stage of recovery, that is if a patient wanted more information on changing medications they could provide treatment choices booklet. – positive feedback from staff and service users. Clinicians stated the benefit of promoting the use of social groups at different points of a patients recovery as they may have been initially apprehensive.

TABLE 49 Normalisation process theory coding frame for phase 3 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
	Internalisation: Sense-making involves people in work that is about understanding the value, benefits and importance of EYE-2.	• Familiarity with existing practice – mirrors EIP ethos – found it an easy transition. • Standardised approach – team has a set approach to work within. • Resources promote staff development – staff that may not have worked with psychosis before have been given booklets and website to learn from. • Positive feedback about resources from staff, service users, families and carers. • Provides professional-looking resources that promotes confidence in the service. • Helps to guide staff when unsure what to talk about with service user – if struggling to build a rapport. • Promotes self-help – if patients have questions they can refer back to resources before asking clinician – helps if patient may be embarrassed to ask. • Shocked with uptake of resources – patients whom they didn't expect to utilise resources have found them beneficial and provided good feedback. • Positive feedback about social groups – patients making new friends with similar experiences.	Clinicians noted that the EYE-2 approach is very similar to existing practices so they didn't have to change much apart from promoting the resources. Clinicians noted the benefits of the resources and have received positive feedback from staff, service users and families. Some clinicians stated that the booklets provide a template on how to structure a session and what information to include when they're unsure. Some clinicians prefer to give the resources as a self-help psychoeducational tool for patients to go through in their own time.
Cognitive participation is the *relational work* that people do to build and sustain a community of practice around EYE-2	*Initiation*: A core problem is whether or not key participants are working to drive EYE-2 forward.	• *Poor attendance of social group leads to a decline in motivation to keep it going.* • *Picking the right time – not using or waiting with patients who have poor engagement, not promoting initially as it may overwhelm patients.* • *Accessibility – patients unable to get to social groups, do not have appropriate technology to attend online or use website, not accessible in all languages, not suitable for everyone.* • *Website not user friendly – unfinished website deterred future use/promotion from staff.* • *Lack of confidence in using motivational approaches – need for more training.*	**Some teams have had really positive experiences of using the social group and patients have given good feedback. However, some teams have stopped promoting or holding social groups as they are poorly attended.**
	Enrolment: Participants may need to organise or reorganise themselves and others in order to collectively contribute to the work involved in EYE-2.	• *Incorporating the booklets and website into standard practice rather than just handing them out – using with patients rather than promoting just self-use.*	*Clinicians had to restructure sessions to utilise the resources with patients rather than just handing them out. These clinicians noted that it didn't make more work they just had to slightly restructure the way they delivered information.*

continued

TABLE 49 Normalisation process theory coding frame for phase 3 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
	Legitimation: An important component of relational work around EYE-2 is the work of ensuring that other participants believe it is right for them to be involved, and that they can make a valid contribution to it.	• *Confidence in approaches and materials – trust resources to provide quality information and build patients confidence in what the clinician is telling them. Confidence in approaches as it mirrors what they were doing previously.* • *Positive feedback from staff, service users, carers and families.* • *Positive feedback promotes further use of resources.* • *Reminds, reassures and reinforces familiar approaches and skills already taught.*	*Clinicians having confidence in resources and positive feedback from patients promoted further use.* *Mirrors existing EIP ethos.*
	Activation: Once it is underway, participants need to collectively define the actions and procedures needed to sustain EYE-2 and to stay involved.	• *Asking for additional training – staff unsure on motivational interviews so have requested more training.* • *Posting booklet resources when unable to give them F2F during lockdown.* • *Making site RA part of weekly handovers so that they can explain any updates and answer questions.* • *Giving patients resource information – revisiting information and promoting use.* • *Using resources in a session with service users.* • *Clinicians revisiting website to ensure they have updated information and can confidently navigate the website.*	*Clinicians noted that they had to proactively ask for training for new staff to ensure all staff knew how to use the EYE-2 resources and approaches. Some teams had high staff turnover, one team noted that there were no staff still at the EIP that had the original training. So ensuring training was up to date was a large part of sustaining the EYE-2.*
Collective action is the operational work that people do to enact EYE-2.	*Interactional workability*: This refers to the interactional work that people do with each other, and with the components of EYE-2 when they seek to operationalise them in everyday settings.	• Accessing resources – ensuring they are seen in a communal area for staff and service users. • E-mailing appropriate person when low stock of booklets. • Training new staff – directing new staff to Ras, giving resources to new staff, sharing information with new staff. Including EYE-2 info in information packs. • Staff discussion – consolidating EYE-2 knowledge, promoting EYE-2 in staff supervisions	Clinicians noted that admin staff were helpful in ensuring resources were restocked – some sites have resources placed in receptions and communal areas. Clinicians have found the presence of having the EYE-2 RA useful. They have directed new staff to the RA's to learn more about the EYE-2. Team leaders have made EYE-2 a subject of conversation in supervisions – reminding that the useful resources are there to make their job easier.
	Relational integration: This refers to the knowledge work that people do to build accountability and maintain confidence in EYE-2 and in each other as they use them.		

TABLE 49 Normalisation process theory coding frame for phase 3 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
	Skill set workability: This refers to the allocation and training work that underpins and is built up around EYE-2 as it is operationalised in the real world.	• Asking for more staff training for MI – including EYE-2 info in staff induction packs – asking EYE-2 site RA to give new staff an overview of EYE-2. • Training useful when attended. • MI training gave a basic understanding – not in depth enough for staff who haven't come across it before – good as a refresher of knowledge. • Showing new staff the resources and where to access them.	A lack of confidence in delivering MI was displayed by clinicians. It seemed that if the clinician had previous knowledge on MI then the training was a good refresher but was not substantial enough for staff who hadn't had any MI training previously.
	Contextual integration: This refers to the resource work – supporting EYE-2 through the allocation of different kinds of resources and the execution of protocols, policies and procedures.	• Ensuring resources are accessible – on display in office and in reception. • Allocating admin staff to keep an eye on resource stock levels.	Some teams identified the importance of making resources easily accessible and visual to promoted maximum use. Also allocating someone to keep and eye on stock levels so they do not run out.
Reflexive monitoring is the retrospective *appraisal work* that people do to assess and understand the ways that EYE-2 affects them and others around them.	*Systematisation*: participants in EYE-2 may seek to determine how effective and useful it is for them and for others, and this involves the work of collecting structured information in a variety of ways.	• *Verbal feedback of resources from staff, service users and carers – mostly positive experiences.*	*The feedback clinicians received about the resources was predominantly positive, however, negatives were that service users didn't use resources. No clinicians noted that the resources had a negative impact.*
	Communal appraisal: participants work together – sometimes in formal collaboratives, sometimes in informal groups to evaluate the worth of EYE-2. They may use many different means to do this drawing on a variety of experiential and systematised information.	• *Useful for staff training – included in induction packs.* • *Team unsure on what EYE-2 actually is – benefit from more training.* • *Good feedback of resources from staff.* • *Managerial roles seem less aware of EYE-2 as they do not have a caseload – they speak from others experiences of using the EYE-2 rather than their own.* • *Staff initially resistant to EYE-2 – something else to do when already busy.* • *EYE-2 didn't feel part of the EIP – separate entity – 'just a research project'.*	Managers with EIP seemed less aware of EYE-2 and spoke from teams experience as they do not have a caseload. Some team members are still unaware of EYE-2 and feel there's no point learning about it as the trial is coming to an end.

continued

TABLE 49 Normalisation process theory coding frame for phase 3 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
	Individual appraisal: Participants in an EYE-2 also work experientially as individuals to appraise its effects on them and the contexts in which they are set. From this work stem actions through which individuals express their personal relationships to new technologies or complex interventions.	◦ *Stopped offering social group as the study is coming to an end.* ◦ *Positive experiences with social group – clients have formed friendships.* ◦ *Positive feedback on booklets from Staff, service users and families.* ◦ *Booklets are good for structuring a session.* ◦ *Memory is a barrier to using EYE-2.* ◦ *Similar to approaches already used in EIP (MI).* ◦ *Benefit from having professional looking resources – creates more trust and confidence in EIP.* ◦ *Positive experiences using treatment choices booklet.* ◦ *Resources are a quality psychoeducational tool.* ◦ *Use resources to challenge clients self-stigmas on psychosis.* ◦ *Worried about resources no longer being available now the study is coming to an end.*	Some clinicians stopped promoting the social group as the study is coming to an end so they do not want to get patients depend on something that may disappear. They are unsure on the next steps after the trial ends. Some clinicians stated concerns that they would lose resources now the trial has finished as they have really incorporated them into daily practice.
	Reconfiguration: appraisal work by individuals or groups may lead to attempts to redefine procedures or modify EYE-2.	• Using EYE-2 with all ages • More training/refreshers • More contact with EYE-2 about developments/changes/updates	*Some clinicians notes that the majority of their caseload was not within the age range for the study – some of these clinicians used the resources regardless of age. However, some had little experience of using the EYE-2 as their caseload was out of the age range and therefore was not appropriate.*
Features of EYE-2	*Plasticity*: The extent to which EYE-2 components are malleable and can be moulded to fit their contexts. *Elasticity*: The extent to which contexts can be stretched or compressed in ways that make space for EYE-2 components and allow them to fit.	• Clients can dip into resources as their own pace – independent use. They can revisit clinicians with questions regarding the content of what they have read from the resources.	
	Coupling: Relations of dependence between people, EYE-2 components, and the contexts in which they are working.	• Clients above age range for the intervention – only has a minority of caseload that is appropriate for intervention – forgets to use it as not using consistently. • Accessibility – patients have problems accessing appropriate technology – do not want to waste credit on accessing website. • Low uptake of social group – leads to a decline in promotion – staff confused regarding low attendance.	Clinicians highlighted accessibility as a barrier to implementing the resources. Having the appropriate technology to access the online resources was challenging – also using online social groups. One clinician noted that social groups were still not able to happen F2F due to COVID restrictions and not having a big enough space to facilitate COVID-safe social groups. Clinicians also found that some languages that they required were not accessible in the resources – notes that this was the same across the board for psychosis resources.

TABLE 49 Normalisation process theory coding frame for phase 3 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
Negotiated outcomes	*Normative restructuring*: Changes to professional norms, rules and resources as a result of working with EYE-2. *Relational restructuring*: Changes to the ways that people are organised and relate to each other as a result of working with EYE-2.	• Use EYE-2 resources in introduction packages with new staff.	
Readiness and commitment	*Individual readiness*: Participants' readiness to translate individual beliefs and attitudes about EYE-2 into behaviours that are congruent, or not congruent, with (new) system norms and roles.	• Caseload not suitable for EYE-2 – (not within age range). • Memory – forgets to give clients resources information – forgets about the EYE-2 – not a priority in sessions – not using consistently. • Haven't familiarised themselves with resources – find other websites easier to navigate/more used to them – out of routine. • Finds resources really beneficial – good experiences have promoted further use. • Lack of personal use – do not have their own caseload – speaking from others experience. • Reminders – need reminders from APs to use and promote resources. • Forgets to collect data so may not reflect actual use.	Some clinicians noted that they wanted to utilise the resources, however, found this difficult due to high workload and pressures. Because of this they have not been able to familiarise themselves with resources so do not feel confident to use them. Clinicians found resources really beneficial when explaining things to service users. Good feedback promoted further use.
	Shared commitments: Participants' readiness to translate shared beliefs and attitudes about EYE-2 into behaviours that are congruent, or not congruent, with (new) system norms and roles.	• Staff attitude – invested in the success of EYE-2 – eager to keep EYE-2 resources. • Staff attitude – not referring clients to social groups as trial ends soon – unsure on what will happen to resources. • Staff have different levels commitment to EYE-2 – use the resources differently across the team. Use with clients vs. give as an independent resource.	Clinicians seemed reluctant to promoted resources because of the trail coming to an end. They seem eager to keep resources and would be sad to see them go as they have slotted in well with routine practice.
Process limiting factors	*External (exogenous) processes* and events that shape the capacity of participants to implement and operationalise EYE-2 (e.g. Austerity, COVID)	• COVID-19 – social group lacked uptake during lockdown and lacked uptake once back to norm – completely changed how they work. • Brexit – change in staff.	COVID-19 has posed as a huge barrier to implementing the EYE-2 as their routine practice has changed frequently throughout the pandemic. – remote working, not seeing patients F2F, working part time in the office. Having to deal with personal COVID-19 struggles.

continued

TABLE 49 Normalisation process theory coding frame for phase 3 process evaluation (*continued*)

General construct	Specific construct	Example themes/subtheme	Summary of code
	Internal (endogenous) processes and events that shape the capacity of participants to implement and operationalise EYE-2 (e.g. staff shortages, strategic initiatives)	• Workload – case increase since lockdown has ended – increased pressures. • Time constraints – struggle to fit in EYE-2 practices. • Memory – remembering to implement EYE-2 (reminding clients to use social group/remembering to give clients information about website and booklets). • Staff turnover – having to train new staff – not as aware of EYE-2/not as invested in the EYE-2.	There was a large amount of staff change over since the EYE-2 trial started – off with COVID, sickness, isolating. Memory was also a huge barrier – staff had so many other things to keep in mind as well as EYE-2. EYE-2 dropped in priorities.

TABLE 50 Example themes and quotes from round 3 of the EYE-2 qualitative study

Themes	Team location and participant number										
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11
Standardised approach		✓						✓			
Clinician relates to EYE-2 approach		✓	✓								
Familiarity with existing EIP practice			✓	✓		✓		✓	✓		✓
Lack of understanding of EYE-2			✓	✓	✓	✓			✓		✓
Accessibility for service users	✓	✓					✓		✓	✓	
EYE-2 not a priority	✓				✓				✓	✓	✓
Memory as a barrier				✓		✓		✓			✓
Confidence in EYE-2		✓		✓			✓				
Workload/pressures	✓	✓	✓		✓	✓	✓	✓	✓		
Benefit from more training	✓	✓		✓	✓	✓	✓		✓		✓
COVID is a barrier	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Uses resources	✓	✓	✓		✓	✓	✓	✓	✓		✓
Uses approaches			✓					✓			
Lack of first-hand use	✓		✓		✓	✓				✓	
Caseload increased	✓										✓
Received positive feedback about resources		✓	✓	✓	✓	✓		✓			✓
Used booklets	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Referred patients to social group			✓		✓	✓	✓		✓		
Used website	✓		✓		✓	✓	✓	✓		✓	✓

continued

TABLE 50 Example themes and quotes from round 3 of the EYE-2 qualitative study (*continued*)

	Team location and participant number										
Themes	**P1**	**P2**	**P3**	**P4**	**P5**	**P6**	**P7**	**P8**	**P9**	**P10**	**P11**
Revisits resources with patient	✓		✓			✓		✓	✓		
EYE-2 improves clinicians' knowledge	✓	✓	✓		✓		✓	✓			✓
Introducing at the start of treatment	✓	✓	✓	✓		✓		✓	✓		✓
Utilised treatment choices booklet	✓		✓	✓		✓			✓		
Staff conversations around EYE-2							✓	✓		✓	
Staff turnover	✓	✓	✓		✓	✓					✓
Found resources helpful	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Notes

*Standardised approach***:** Clinicians mention the benefit of the EYE-2 collating existing practices into a standardised approach so that all employees work similarly.

*Clinician relates to EYE-2 approach***:** Clinicians relating to the EYE-2 on a personal level that is within their own set of principles.

*Familiarity with existing practices***:** The EYE-2 approaches are similar to existing EIP practices.

*Lack of EYE-2 understanding***:** Clinicians admission that they lack understanding of what the EYE-2 is or how to use the resources appropriately. Also including struggling to explain what the EYE-2 approach is.

*Accessibility for service users***:** This includes accessibility in terms of service users having appropriate technology to use resources and also challenges in the location of social groups. Language barriers is also identified within this theme.

EYE-2 not a priority: Clinicians suggesting that the EYE-2 is not a priority due to COVID-19 and high workload. Clinicians noting other responsibilities are more important to complete rather than focusing on the EYE-2.

Memory as a barrier: Clinicians identifying that remembering to use the EYE-2 approaches and resources is a barrier to use.

Confidence in EYE-2 approaches: Clinicians level of trust towards the EYE-2.

Workload and pressures: Clinicians identifying that high workload and pressures are a barrier to using the EYE-2.

Benefit from EYE-2 training: Clinicians mentioning that they would benefit from more training around MI and general EYE-2 training. Also includes clinicians who haven't previously attended EYE-2 training.

*COVID-19 as a barrier***:** Clinicians suggesting that COVID-19 has been a barrier to using the EYE-2 as it posed extra strain on staff.

*Use resources***:** Using and integrating resources in daily practice with all caseload. This includes using one or more of the following: booklets, website and social groups.

Use approaches: Using and implementing MI resources into daily practice with caseload.

Lack of first-hand use – Clinicians who state they have a lack of personal experience using the EYE-2 approaches and resources or speak from other team members experiences of using the EYE-2 throughout the interview.

Caseload increased – Clinicians identifying an increase of caseloads while implementing the EYE-2.

Staff turnover – This includes clinicians that mentioned staff turnover to be high during the time that the team was implementing the EYE-2.

Received positive feedback about resources – positive feedback received from service user, families and carers regarding any of the EYE-2 resources (booklets, website, social group).

Used booklets **–** Clinicians identifying that they have used the booklets with service users, families, carers or independently. This is either within a session with someone or giving the booklets out for independent use.

Referred patients to social group – clinicians who have mentioned actively referring patients to the social group resource.

Used website – Using the website by either going through the information with a service user, families or cares within a session or giving them the information to go through it independently. This also includes clinicians who have used the website independently.

Revisits resources with patient – Clinicians that revisit resources with patients at a future date. This may include clinicians who have revisited on one occasion or multiple.

Resources improve clinicians' knowledge – Clinicians that identify the benefit that the EYE-2 has improve their own knowledge or other staff member knowledge.

Introducing at the start of treatment – Clinicians that state introducing the resources and approaches at the beginning of treatment, they may revisit the information at a later date.

Utilised treatment choices booklet – A specific mention of the treatment choices booklet being beneficial to the psychoeducation of patients.

Staff conversations around EYE-2 – Discussions amount staff around the EYE-2.

Found resources helpful – Clinicians identifying that themselves or their team have found any of the EYE-2 resources helpful.

Key quotes – Round 3

Standardised approach – NPT: Coherence (differentiation)

P2: 'Do you feel that there have been any benefits to you as a clinician having worked with the EYE-2 approach over the past few years?

P2: I've worked in EI services . . . forever. And you don't want to be really egotistical and like I know everything but I think specifically for the kind of more recently qualified staff that haven't worked in EI before there has been more of a benefit. Because like I say it's something to refer back to, it's a standardised resource'.

P08: 'P08: Yeah I do think they fit in really well. I don't think when we had the training that it was anything that was massively different to what we were already doing anyway but in addition to that it just kind of gave us an extra layer of information and maybe refreshed our mind on different ways we can interact with patients.

RA: Yeah, that's great. That sounds really positive. So erm . . . oh sorry. Erm how do you feel the EYE-2 approach and materials changes the way that you and your team works?

P08: Erm . . . I think that it's probably again just enhanced the way that we work in some ways because we can give people information in ways that we didn't before'.

Clinician related to EYE-2 approach – Cognitive participation (legitimation) and coherence (internalisation)

P2: 'But yeah I've obviously found it useful but for me a lot of it makes sense and that's why I believe in the resource, I like the resource and that's why I recommend it to people. But I think it's probably been kind of more useful for staff that aren't as familiar with working with people with psychosis'.

P3: 'So thinking about you team how do the attitudes of staff, service users or carers towards the EYE-2 approach and resources influence whether they're used?

P3: Erm . . . I mean as I said before, obviously if we had staff members who were unmotivated . . . erm either to use the resources or to work collaboratively with service users and their families kind of to inform their choice and give them

information, then I would . . . erm suspect it would be, it would be quite tricky. But again, yeah it's just, it just had been inline . . . there is already a very strong ethos of collaboration and giving information and sort of family engagement'.

P4: 'How do the EYE-2 approaches and resources fit with the way you and other staff feel you should be working and within the standard EIP ways of working?

P4: Yeah I guess I've already answered that in the one before. Like I do agree that it fits in well with our principles and the way we work'.

Familiarity with existing EIP practice – Coherence (internalisation)

P3: In terms of the approach . . . I mean again I think that the EYE-2 approach is, is just from what I, I don't remember very much about the theoretical approach other than it matched entirely with what we were already doing. So I think that kind of went in one ear and out the other ear if that makes sense . . . . Because I was sat there and I was like, yep yeah . . . that's what we already do. So, so there certainly hasn't been any resistance but at the same time there hasn't been any reason to change because it's been in line with what we've already been doing.

P08: 'RA: How do you find the use of EYE-2 approaches and resources when there are other demands and pressures?

P08: Erm . . . I think, I suppose when you think about sort of motivational interviewing we kind of use that a bit already anyway, so I guess some of the stuff is what we should already be doing. We should be trying to engage people, we should trying to kind of build therapeutic relationships and use motivational interviewing where appropriate'.

P09: 'P09: It's kind of an additional pillar to support what we should be doing in the first place. It's not anything kind of really different. Erm more so just resources to support what we are telling people'.

P11: Yeah so I think it's always good to have extra resources in place and I think it's always good to know you can go back to the resources with the clients and you can kind of go back to it when you need it. I think it's kind of reinforced some of our staffs knowledge as well, especially I think it could be good for the people new to the team . . . but I've worked in EIP for like seven years so it's kind of what I already knew but they are still really helpful for service users to use.

Lack of EYE-2 understanding – Reflexive monitoring (individual appraisal) and collective action (skill set and workability)

P3: 'Do you remember anything about the training slides, manuals or the engagement approaches used?

P3: Erm, no not really. Erm, it's been about two years since I did the initial training so no I don't to be honest remember much about that.

RA: No, that's absolutely fine. Erm, so what do you know or remember about the EYE-2 approach and resources?

P3: So, erm I mean I'm reasonably familiar with the booklets. That's been the thing from the trial that I have used the most. Erm, I . . . yeah, I've really found in particular the . . . I'm just trying to think of the names of the, the the big blue one that's all about the treatments'.

P4: 'Do you remember anything about the training slides, manuals or engagement approaches that were spoken about in the training?

P4: To be honest I can't actually remember anything that we did. I think it was probably about two years ago that we did the training. All I remember about the EYE-2 is the stuff from actually reading the leaflets'.

P5: 'Is there anything that could be provided to help you to know more about using the EYE-2 approach and resources?

P5: Yeah I think, and I was talking to = AP = about this, erm is that we need to know . . . what we need to know is what the project is before we have the EYE-2 staff member in post so that they can come and talk about EYE-2, what it is, how it benefits service users, what they need from us . . . erm and just go through it because I still think a lot of the team still don't know what it is'.

P09: 'I joined the team back in august so I missed the initial training and erm the refresher training I think as well. Erm so I just received some kind of ad hoc information.

RA: Okay is there anything you can tell me about the kind of ad hoc info that you got?

P09: I didn't get much in all honesty. Erm not much at all. So erm I could probably do with some training actually haha'.

P11: We've had a lot of turnover and people coming back from erm . . . and we've had a lot of new starters. About four actually just starting in the last month, which is good actually but I wonder if they might need a refresher or maybe they aren't aware of it. that would be good, I don't know if you could come back and do another training.

Accessibility for service users – Cognitive participation (initiation)

P1: 'It's when somebody's expected to get somewhere. I think that's what's been the difficulty with the EYE-2 groups. It's that service users, you know, still find it very difficult to motivate themselves and if they've got to use public transport they . . . tend not to. They will just stay at home rather than getting there themselves'.

P2: 'The website has been more difficult to use because not everyone has internet access. We've got really rubbish mobile phones that we can't get on the internet with to sit with someone and show it to them. It just, it feels less accessible, erm . . . and again with the groups. I don't know that we've ever had my information about the groups, again probably due to COVID it's not been something we've been able to engage with'.

P2: 'But for me personally what I would like to see is some slightly more accessible resources. Erm, so I think we have issues with kind of Autism and that type of neuro-dev, rather than capacity. We are quite a young person team, we don't tend to get many capacity issues but you know all EI teams are I guess. But something to . . . kind of help autistic people. Something a bit more visual maybe, erm . . . we would definitely benefit from'.

P2: 'Erm you've got them online in a lot of different languages and we've spent a lot of time on there looking for erm some of the languages we wanted to find but some of them just weren't on there. We've got such a diverse service user population there's probably five or six languages that we've just not been able to get the resources in. But these are languages that our interpretation services can't even provide anyone to us to interpret for us. So . . . it's not, it's not like a massive . . . it's not kind of a slight on EYE-2, it's just we have some really obscure languages'.

P2: 'Yeah, we've got, we have a lot of students and stuff but internet access is surprisingly challenging for a lot of our population. We've got a lot of young people that don't even have contract phones. They don't have the internet at home. It's probably kind of a socioeconomic thing as well. They just don't have internet access readily. And with COVID and library's being closed and everything else we are really struggling to get people online. We've got people that we are just going out to see just to bid on houses for them weekly because they can get on the internet to do it themselves. So I think internet access is not something that you think of as a problem in this day and age with the service user group but it really really is'.

P07: 'RA: So how well are the EYE-2 approach and materials suited to being used in a remote working approach?

P07: I think it's difficult. Erm just because you've got so much stuff to make sure that you've got with you and its more difficult to get to the patients. Erm yeah like I said some patients don't have the appropriate technology to be able to get the resources only so that can be difficult'.

P09: 'P09: With the groups it's been difficult because they were originally at physical locations and now obviously with COVID they've had to be held over teams which has pros and cons. Pros being that obviously people that won't come out of the house can then attend or for different reasons like they can't get to the location I suppose it makes it easier. But erm cons being that it's always nice to encourage people to get out and see people face to face . . . From conversations from my colleagues it seems people preferred it when it was face to face and more people attended'.

P10: 'P10: We do have some families and clients that won't or can't use more online based resources like the social group since moving to teams because of COVID. So that kind of limits their accessibility to resources and often they're the ones that we are working hardest to engage the most but maybe they don't have the tech to use the online stuff or knowhow to get on these websites so it can be really difficult for those people'.

EYE-2 not a priority – Process limiting factors (external and internal processes) and readiness and commitment

P1: 'So things like EYE-2 sort of . . . it wasn't a priority it was just trying keep people as well as possible and support them in a really difficult time . . . I think COVID, yeah COVID definitely had a role to play in this'.

P5: 'What was your experience of implementing the EYE-2 approach and EIP more broadly during lockdown compared to before COVID?

P5: I think it again was just very basic because at the beginning not many people wanted to be seen face to face, they were obviously offered it . . . but we were very limited in the amount of people we would see and it just wasn't the priority. So it had reduced in somewhat but now it's coming back again'.

P09: 'So is there anything that gets in the way of using the resources or approaches at all? . . . So maybe attitudes of staff or service users, or service demands or pressures?

P09: I think maybe attitudes of staff because when anything like this is introduce, you know like a study or a new approach I think people can think that it's just another thing they've got to do. Another thing to add on top of their caseload. So then it might go down on the priority list so to speak. But things like the booklets and the social group and things like that they're really very useful and it doesn't take a lot of work to give someone a booklet to look through and then maybe when you next see them bring up a discussion about the booklet, see what they thought, just go over the content and see what they understand. It's a good way to get people engaged as well because sometimes it can be difficult to find things to talk about'.

P10: There is so many other priorities at the moment so it's really difficult, especially given the pandemic and the referrals have probably gone up about a third I'd say.

P11: I think erm sometimes we have so much to get through in a session with someone that it can kind of be left behind, erm you can just kind of maybe forget about mentioning it a little bit. And then once the persons gone you'll think oh I wish I gave them the resources but sometimes there's just not enough time.

Memory as a barrier – Readiness and commitment

P4: 'Is there anything that gets in the way of using the approach and resources? . . . so maybe service demands, pressures, that kind of thing?

P4: Yeah that's is basically the main thing that I was going to say is . . . it is the service demands, it's that care co-ordinators don't have enough time to remember to pick up a leaflet or have time to remember to remind their service users about the social groups, that is the main obstacle'.

P5: 'Is there anything that gets in the way of using the approach and materials?

P5: Erm . . . forgetfulness that they are there. Erm so again it's about reminding each other that we do have these leaflets, we do have this website that a really good resource'.

P08: 'RA: Is there anything that gets in the way of using the approach and materials? So maybe service demands, pressure, maybe even attitudes of staff and service users?

P08: I think again it just depends on . . . I think everyone's just so busy and we've got lots of different paperwork to complete with patients and I think it's just like I say keeping it fresh in people's minds that we've got these resources there and they've been produced and a lot of work has gone into them and they're really relevant to our service. That's kind of how I feel about them. But erm yeah I think mainly the barriers are people time and remembering that they're there. Erm I'm trying to think of . . . erm and yeah I guess the website just remembering that it's there and giving people the information to be able to go and seek it out. But yeah I just think there's so much for us to remember as clinicians and maybe sometimes for some people they just think it's another thing for us to remember. But actually if you frame it differently and think actually it's something that can really help the patient and us'.

P11: I think erm sometimes we have so much to get through in a session with someone that it can kind of be left behind, erm you can just kind of maybe forget about mentioning it a little bit. And then once the persons gone you'll think oh I wish I gave them the resources but sometimes there's just not enough time.

Confidence in EYE-2 – Reflexive monitoring

P2: 'People generally receive it quite well and are erm, really grateful for the information. I think people trust a professional looking book more than they trust us telling them something. I think it really helps our, really helps our impression of our team and service when we've got something to hand out. So, it's been really well received'.

'What is the value of the EYE-2 to you, your service users, families and your team?

P2: Honestly it sounds proper cheesy but at this point it is like invaluable, like I'm already wondering and wanting to ask like what happens when this finishes?, do we continue getting the resources?, Is this being rolled out?. Erm, cos it would be horrible if it was taken away. You know it's part of like, you know every care co-ordinator has got a pack of the outcome measures in their car. Like its just become part of what we do, it's just become invaluable'.

P4: 'How much trust or confidence do you have in the EYE-2 approach and resources?

P4: Yeah, lots lots. Very confident'.

P07: 'RA: How do you feel that the EYE-2 approach and materials have changed the way you and your team works?

P07: Well I suppose it's kind of it, the materials are helpful in backing up what we say to the patient and it's there for them to look as well which I think it really useful. [inaudible segment] . . . yeah for us it gives us a nice introduction to things. Like I said before really haha.

RA: Yeah so it kind of helps you introduce things to the patients and [cross talk]

P07: Yes and it also makes EIS more erm this has evidence, making it a bit more erm sort of . . . erm how can I say . . . erm it perhaps makes it sound a bit more relevant or trustworthy and helps erm show that each intervention is evidence based.

RA: Okay so is what you're saying that it gives people more confidence in what you are telling them?

P07: Yeah absolutely'.

Workload/pressures – Readiness and commitment (individual readiness) and process limiting factors

P1: 'I think it's just that, I think it's weird cos it was like erm . . . it was the acuity of the number of referrals, they weren't necessarily appropriate for us but I think it was just the number of assessments people were having to do. So we weren't taking on the same number of people that we might have done historically . . . I think, I I do think that there's a lot of people with psychosis, because they weren't seeing family and friends and they were isolating at home. You know, there's a lot of hidden, hidden psychosis there and that will start coming out of the woodwork over the next erm, the next few months, you know the increase of referrals will come in the next few months'.

P2: 'How did you find the use of the EYE-2 approach and resources when there were other demands such as caseloads?

P2: I think it actually assisted. Erm so it was part of the project that people were helping us, especially at the beginning we seemed to have more contact, people were helping us by contacting erm service users and completing outcome measures. Which was really really helpful when our workload was really really erm high'.

P3: 'I think one of the things I've been conscious of is having the time to do some of the outcome measures that have been needed have been an absolute nightmare to be honest with you. Erm, so I guess . . . I'm glad of the opportunity to do this and feedback how helpful I have observed the resources to be and, but I suspect that the outcome measures don't support that because I just don't have the time to do them if I'm honest'.

P3: 'It's very difficult at the moment to pick out what is Brexit and what is COVID. Yeah so there are increase pressures on the service, there are increased pressures nationally within our national culture at the moment which is putting pressure on peoples mental health, which I think is driving up referrals across the board for mental health services not just for psychosis services. So I suspect there is some degree of subtle impact but there isn't anything that I would directly say is well that's Brexit'.

P5: 'How much trust or confidence do you have in the EYE-2 approach and resources?

P5: Oh I do think we have a lot of confidence and trust in the research project. I just think sometimes we are lacking in knowledge of what it is and what we are doing with it. We just need that reminder.

RA: Yeah I can understand how that would be a real barrier.

P5: Yeah and I think that when someone hears research they just think, oh well I just haven't got time for that right now. But when they hear that it is beneficial for service users then they will . . . but obviously it also depends on time'.

P6: 'What about service demands or pressures?

P6: Yeah but I think that falls in the kind of humanistic factors of when I say forgetfulness. So demands and staff feeling overwhelmed but actually when they're feeling overwhelmed the resources are there to actually help them.

RA: Yeah of course.

P6: But yeah I think that falls in to kind of human factors of feeling overwhelmed, feeling busy, forgetting. And that's why it's always good to remind people that they are there and that they are a good resource. It's about me introducing them to new staff as well, making sure they're part of the introduction'.

P07: 'RA: Is there anything that gets in the way of using the approach and materials such as service demands or pressures?

P07: It's a lot to carry around with you all these brochures and stuff in your car so you can have it when you need it haha. So it needs a bit of co-ordination. It was particularly difficult during COVID, when you've got one day in the office

and one day not to have the all readily there. So its organisation about the brochures that definitely something that needed good planning as a care co-ordinators'.

P08: 'RA: Is there anything that gets in the way of using the approach and materials? So maybe service demands, pressure, maybe even attitudes of staff and service users?

P08: I think again it just depends on . . . I think everyone's just so busy and we've got lots of different paperwork to complete with patients'.

P09: 'RA: So is there anything that gets in the way of using the approach and materials? Erm so maybe service demands or pressures . . . or maybe attitudes of staff?

P09: I think maybe attitudes of staff because when anything like this is introduce, you know like a study or a new approach I think people can think that it's just another thing they've got to do. Another thing to add on top of their caseload'.

P11: RA: Is there anything that gets in the way of using the EYE-2, maybe service demands or pressures?

P11: Yeah so we've been quite busy as a service, we have like 290 in our caseloads and I think definitely we can feel like we feel there is too much to do sometimes. So it doesn't give as much time to go over them.

Benefit from more EYE-2 training – Collective action (skill set and workability)

P1: 'I've been trying to organise some additional and more in-depth motivational interviewing training as well cos I think that bit was really erm . . . was like was really relevant I guess to this and the other work we are doing in the EI service as well'.

P2: 'What do you know or remember about the EYE-2 project training?

P2: Oh, it was a while ago. I remember that the staff that went on it found it really useful . . . erm I think on reflection I should of probably asked for it to be repeated because we've had quite a high staff turnover and we've not actually got any staff left that erm completed the training'.

P2: 'Maybe the groups and the websites, like I say if it's going to continue it would be useful to . . . relearn how to access those and maybe arrange some training for the staff'.

P3: 'Okay so is there anything that you remember about the EYE-2 approach and resources?

P3: Erm . . . EYE-2 intervention approach and resources . . . yeah so I guess my understanding of the EYE-2 . . . oh yeah and just in terms of the training by the way I think they have actually offered and provided another EYE-2 training since but I wasn't able to attend'.

P5: 'I think the problem is the EYE-2 project staff come in and I don't necessarily manage them and they just come in and they, I think they expect us to have this knowledge and we don't really so I think we would benefit from going back to basics if that makes sense'.

P07: 'RA: So what else could be provided to help you know more about using the EYE-2 approach and resources?

P07: So for me particularly it's the age erm range. More catering for the different age range. Erm what else would be helpful, erm . . . yeah so I think it's also timing, erm you know saying this is something for life, it's kind of something to look back on, you know. Perhaps more explaining it like that . . . .And it's also like you've got so many different brochures which is great but maybe something to help the care co-ordinators realise when to use them. So the one that's got all the interventions, erm and to perhaps feed them, [inaudible segment] . . . But for example CBT for psychosis we know there's a delay, we know there is a waiting list. So that could have been a bit more carefully put into erm. . .

RA: Okay so do you think maybe a bit more training for the care-co's and when to use the different resources?

P07: Yep, definitely'.

P09: 'P09: I joined the team back in august so I missed the initial training and erm the refresher training I think as well. Erm so I just received some kind of ad hoc information.

RA: Okay is there anything you can tell me about the kind of ad hoc info that you got?

P09: I didn't get much in all honesty. Erm not much at all. So erm I could probably do with some training actually haha.

RA: What else could be provided to help you know more about the EYE-2? I guess training haha?

P09: Yeah haha training would help. Erm so I kind of knew about the resources and the social group and the motivational interviewing so it was really just the training that was missing for me'.

P11: We've had a lot of turnover and people coming back from erm . . . and we've had a lot of new starters. About four actually just starting in the last month, which is good actually but I wonder if they might need a refresher or maybe they aren't aware of it. that would be good, I don't know if you could come back and do another training.

COVID is a barrier – NPT: Process limiting factor (external processes)

P1: 'The groups erm.. have been a bit more difficult . . . because we are such as dispersed and large locality is very hard to run any groups and draw in service users into those. I think COVID obviously hasn't helped . . . .And . . . erm the EYE-2 research assistance in our area, have, have tried their hardest to, to you know, encourage service users to join and participate and you know move to online groups when COVID was its worst. But that's, that's definitely been more difficult . . . So attendance has been quite poor'.

'Is there anything that gets in the way of using the approaches and materials? So maybe service demand or pressures, attitudes of staff and service users erm, that kind of thing?'

P1: Erm, well I think COVID, definitely. Erm . . . I think we would of, I think we would of really benefitted from additional training around motivational techniques. Erm the EYE-2 training was really helpful with that but you know, it just touched the surface I guess. And I think we . . . we didn't have the funding to actually you know train the whole team to do that, so a couple of people have done it but not everyone. But you know, I'm still trying to fight for that, I'm still trying to get funding for that two years later'.

P2: 'What else could be provided to help you to know more about using the EYE-2 approaches and resources?

P2: I think potentially, I mean I don't know if it's, I guessing its largely due to COVID, I think . . . in line with us having such a high staff turnover and everything that's happened in the last 18 months. I think it's been really easy to use the written resources, they've been really useful and really handy but I think for the rest of it, maybe having . . . a link person some in . . . or have a bit more contact from somebody from EYE-2 just to remind us what there is. Erm and like I say kind of refresher training or kind of rerunning the training when we got new staff would have been helpful'.

P3: 'I'm aware of in terms of the social group things now at this kind of end stage are now getting up and running again, it has been kind of unfortunate that COVID happened when it did in terms of our participation in the EYE-2 trial. Because I don't think that, although the staff members running it have done the best that could within the circumstances, I don't think the social group has got off the ground . . . erm as much as, you know it's just finding its feet now and getting some participation but erm I imagine that could of happened much more quickly and been much more established now with a higher kind of participation had we not been in eighteen months of lockdown in the middle'.

P4: 'Is there anything that you remember about the website or the social group resources at all?

P4: I don't really remember anything about the website to be honest. Erm . . . and in terms of the social group, I know initially it was really helpful but obviously it was massively impacted on by the pandemic. But yeah I know initially I think it was a peer led social group and it was really popular but I guess my impression is that perhaps it's been harder to facilitate because of the pandemic, not that that should be an obstacle for it continuing'.

P5: 'How does the use of the EYE-2 approach and resources fit with other demands on you time and other things you need to do when working with service users?

P5: I mean again I think . . . you know we will endeavour to use it but if you know we are stretched with staff being off sick or with COVID it's probably on the bottom of peoples lists'.

P07: 'RA: Is there anything, erm you've mentioned this slightly already but is there anything that gets in the way of using the approach and materials such as service demands or pressures?

P07: It's a lot to carry around with you all these brochures and stuff in your car so you can have it when you need it haha. So it needs a bit of co-ordination. It was particularly difficult during COVID, when you've got one day in the office and one day not to have the all readily there. So its organisation about the brochures that definitely something that needed good planning as a care co-ordinators'.

P08: 'RA: What was your experience of using the EYE-2 resources and materials during COVID-19 and the lockdowns? Did your use increase or decrease?'

P08: Erm I suppose the booklet side of things may have decreased just because you're not seeing as many people. Erm . . . but I don't actually know. Erm I guess a lot of my, erm we still continued seeing people all throughout the lockdowns even if it might have been at a distance or kind of a lot of telephone assessments and appointments took place. For our more seriously unwell patients we were still seeing them face to face. But I'm wondering if overall it probably decreased a bit. Erm just because of the situation we are in and we were just having to do the bare minimum of contact in the service at the time'.

P09: 'P09: With the groups it's been difficult because they were originally at physical locations and now obviously with COVID they've had to be held over teams which has pros and cons. Pros being that obviously people that won't come out of the house can then attend or for different reasons like they can't get to the location I suppose it makes it easier. But erm cons being that it's always nice to encourage people to get out and see people face to face . . . From conversations from my colleagues it seems people preferred it when it was face to face and more people attended'.

Uses resources – Reflexive monitoring (Individual appraisal|) and readiness and commitment

P1: 'The . . . erm I mean, I think the leaflets have been invaluable, they've been excellent. We've, you know we've used them regularly, erm you know I'll be honest as well, we've actually used them with over 35s as well as an introduction to . . . psychosis, and Early Intervention for Psychosis teams and the sort of possible treatments available. And they've been really well received by service users and carers . . . yeah so they've been an excellent resource'.

P2: 'I know the written resources have been really really useful. We've built them into our kind of initial packs. So we give them out to people when they are accepted. Some are more generic mental health problems, so we take them out on assessment because it doesn't necessarily suggest that somebody's got psychosis. It's more of a useful resources for anyone with mental health problems really'.

'How do the other elements within your day to day practice fit around using the booklets? Again I think you may have touched on that slight but if you could just . . . give me a bit more detail on what that might look like?

P2: It feels . . . it definitely felt at the start like we kind of based, we kind of altered our kind of approach to new referrals based on the resources. So they're kind of our go to resource. So it standardised it a lot for us really because

everybody's getting the same thing, everybody's getting the same information and if another practitioner goes out they know what that persons been told because they know what's in the booklet, if that makes sense'.

P3: 'Is that the treatment choices one?

P3: Yeah that's the one. I mean I really do genuinely use them, I have a stash of them in my car. I give them out to patients and you know, family members that are new to the service. And I erm, I will continue to do that even post the trial. And I have found those resources erm, really really useful'.

P5: 'How do you use the EYE-2 approach and resources, maybe thinking about anyone you are aware of using the resources more than once with the same person?

P5: We have actually. I'll tell you what I did do, when they first came out I was doing a physical health assessment and we were given the booklets and erm I gave one of the booklets, erm we went through it together because it told us about psychosis. So I used one of the booklets to explain, because it was kind of a really easy way of explain it. So we went through it together and yeah I do remember doing that. Erm so I have done a bit, a tiny bit haha'.

P6: 'But I would like to introduce it early as possible. Erm kind of when we do that talk about why we are there, like when they're like "well I don't have psychosis so I don't know why you are here" and then it's about that psychoeducation. So it's used at every stage of someone's journey cos actually the resources are there at every stage and aspect of their journey because they're there when you are considering treatment and when you're thinking about what is psychosis to how does this impact on my family or how can I help someone. So actually the resources are helpful for every part of the patient journey and you can introduce them when appropriate. And I think it is dependent on where your service user is in their journey and where their families are in that journey as to what booklet you introduce, when you introduce the website. But we try to do that as early as possible'.

Uses approaches – Reflexive monitoring and collective action (interactional workability)

P3: 'What was your experience of using the EYE-2 approach and materials during the COVID-19 lockdown? Erm did your use increase or decrease?

P3: Erm it definitely decreased in terms of the written resources during the period that we were doing fewer face-to-face contact. That being said we were tending, apart from the first couple of weeks of COVID we were still tending to see face-to-face new clients because those were often the ones were the risks were a bit more unknown and the engagement approach, a more active engagement approach was necessary.

RA: How do you find the use of EYE-2 approaches and resources when there are other demands and pressures such as caseloads?

P3: Erm, yeah again . . . I don't think particularly . . . the pressures I don't think especially impact on my use of the approaches and the resources. I suspect that yeah the only thing it impacts on is my ability to do the outcome measures.

RA: Yeah.

P3: Erm . . . because the rest of the stuff, the approach and the information giving is just such a core part of what the work is that I would be doing it whatever, you know.

RA: Yeah, so those aspects . . . the things you've mention kind of come naturally?

P3: It just is what the job is . . . it just is what care co-ordinating somebody in Early Intervention services is, it's that engagement approach that kind of facilitating that you know the more social engagement side of things and giving the appropriate information . . . that's what working in early intervention should be'.

P08: 'RA: How do you find the use of EYE-2 approaches and resources when there are other demands and pressures?

P08: Erm . . . I think, I suppose when you think about sort of motivational interviewing we kind of use that a bit already anyway, so I guess some of the stuff is what we should already be doing. We should be trying to engage people, we should trying to kind of build therapeutic relationships and use motivational interviewing where appropriate'.

Lack of first-hand use – Readiness and commitment and process limiting factors

P1: RA: 'So, are you currently using anything from the EYE-2 project?

P1: So, I'm not . . . I mean I'm not working directly with the team now. I mean I'm working across the four. But I know, I know yeah that they are still using the booklets across the team but aside from that I'm not sure to be honest'.

P3: 'What would you say is the element that has most significant impact for the client?

P3: Erm, for my, again because I don't have any direct experience of working with people that have attended the social group, the stories that I hear coming out of the social group are fabulous and I can really imagine the impact that that's making. Erm one of our? STR? workers who, who's part of the social group every week comes back with these fabulous tales of different service users coming along and meeting each other and really forming, having really positive interactions any you know, really . . . erm positive activities. That being said none of my service users are part of that so for me . . . it's been the information giving side of things'.

P5: 'Can you think of any particular ways of how you've introduced anything after being advised by the EYE-2 RA?

P5: No, no I wouldn't be able to tell you that. Sorry.

RA: No that's okay.

P5: Because I'm a manager and not one of the real workers, haha. I just wouldn't be able to tell you that.

RA: Haha, no that's absolutely fine.

P5: I'm sure there is but I don't have a caseload so . . .'

P10: 'P10: So I think maybe I use it less because when I'm brought in to a patients referral or erm treatment its normally a more specialised case of someone that's potentially quite ill or has been challenging in terms of treatment. So in that instance we are kind of looking for quite particular information that I might not get from more generic psychosis resources. So I probably haven't used the resources as much as my other erm colleagues'.

Caseload increase – Process limiting factors

P1: 'COVID like really did put sort of different pressures. And you know, every time there was a lockdown we had a huge increase of referrals to the service, which didn't help. And you know the sort of different demands put on the team and the sort of acuity of referrals as well. Like you know, they had a lot of referrals coming from inpatient services'.

P11: RA: Is there anything that gets in the way of using the EYE-2, maybe service demands or pressures?

P11: Yeah so we've been quite busy as a service, we have like 290 in our caseloads and I think definitely we can feel like we feel there is too much to do sometimes. So it doesn't give as much time to go over them.

Received positive feedback about resources – NPT: Coherence (internalisation)

P02: 'P02: . . . we ask for feedback on it and if we got any feedback that you know it could include something else or something could be changed then we would share that with the research assistance. But there's been nothing, people generally receive it quite well and are erm, really grateful for the information. I think people trust a professional looking book more than they trust us telling them something. I think it really helps our, really helps our impression of our team and service when we've got something to hand out. So, it's been really well received'.

P03: 'RA: How have you decided whether or not the EYE-2 is helpful for service users?

P03: Erm.. how have I decided? . . . I mean for me the experience of saying to a service user to have a look at the website and in the next session seeing if they have had a look and they have. And them saying they've had a look and have some questions about things. That doesn't happen all the time as you can imagine with service users so the kind of feedback that I get that service users aren't using it all of the time but some of the time when we advise them to, yep that's enough for me to feel like it's useful'.

P04: 'P04: In terms of feedback from staff, the feedback from staff has been very very positive in terms of the leaflets'.

P05: 'RA: How do the attitudes of staff, service users or carers towards the EYE-2 influenced whether they're used?

P05: I think there's feedback and we have had some feedback which was positive . . . I don't know if we got any negative but obviously if we had we would of looked and seen if it was something that we could look at and do differently'.

P06: 'RA: If you've given a resource to a service user, how would you know whether that has been beneficial for them?

P06: It's the feedback from them isn't it. Like you know I'm going to leave you with this and next time we will see how you've gotten on. And then people come back and say well I've gone away and read and I can see what you've been saying from this point of view'

P08: 'RA: Have you had any feedback from service users or carers about the resources that you've given them?

P08: Yeah I have. I think people have found them to be really helpful and comprehensive. Erm yeah really good overall I've had nothing negative at all'.

P11: RA: What was your experience of using EYE-2 approaches and resources during COVID-19 and the lockdowns?

P11: I think that erm, I think that it probably did increase because it was an extra thing that we could offer to support people. Erm because we obviously weren't able to see people face to face. Erm so that was really helpful to have because everything's becoming so digital so it was accessible in that way. And I remember people being happy to have it in that way and I had a lot of positive feedback. So I think it did increase.

Used booklets – NPT: Cognitive participation (activation)

P01: 'P01: I think the leaflets have been invaluable, they've been excellent. We've, you know we've used them regularly, erm you know I'll be honest as well, we've actually used them with over 35s as well as an introduction to . . . psychosis, and Early Intervention for Psychosis teams and the sort of possible treatments available. And they've been really well received by service users and carers . . . yeah so they've been an excellent resource'.

P02: 'RA: Are you currently using anything from the EYE-2 project?

P02: Yeah, all the booklets and the outcome measure packs.

RA: . . . is there any booklets you use more or erm . . . stand out to you as being the most helpful?

P02: They're genuinely all really useful, we use all of them. We kept running out so we've had to order some more, haha . . . .It feels . . . it definitely felt at the start like we kind of based, we kinda altered our kind of approach to new referrals based on the resources. So they're kind of our go to resource. So it standardised it a lot for us really because everybody's getting the same thing, everybody's getting the same information and if another practitioner goes out they know what that persons been told because they know what's in the booklet, if that makes sense'.

P03: 'RA: How do you feel the EYE-2 approach and materials have changed the way that you work and the team works?

P03: Erm . . . I don't think they have to be honest in terms of having to do anything new . . . again I do think that erm, to be honest I don't know why we didn't have this kind of information in booklet form and in you know leaflet form and things, erm you know . . . for people before. It seems ridiculous but we didn't, erm so it just is . . . yeah just as I said before just to be able to give professional looking information to people I think is just really really reassuring and just sort of quite helpful to me in terms of you know it comes with a degree of gravitas and you know just . . . look at this resource . . . erm so yeah'.

P04: 'P04: Erm . . . . I think the one, So there's one for carers, one for service users and one for medications, what's the other one?

RA: Is that the treatment choice one?

P04: I think that's the one I'm thinking of for medications. I think the one we use the most is the one for service users but I think also the really big thick one is really helpful as well I think'.

P05: 'RA: So what has helped you to know how to use the EYE-2 approach and resources?

P05: Well we had the training. Erm obviously we were given the booklets. When we were given the booklets I did actually keep them on my desk and I kept on giving them out. Erm but obviously I can't answer that for the other care co-ordinators'.

P06: 'RA: Are you currently using anything from the EYE-2 project?

P06: Yes, I'm using the booklets and the website resources'.

P07: 'RA: Are you currently using anything from the EYE-2 project? I know you've already touched on this a little bit but if you don't mind elaborating.

P07: Yeah so I do still refer new patients to use the overall brochure but I use it differently now. The carers one I also think it pretty good so I do use that. It's a snapshot of things but not overloading. Erm I particularly like that one for carers. Erm, so erm yeah so I think it's the timely kind of when you introduce things again which is important'.

P08: 'RA: Are you currently using anything from the EYE-2 project?

P08: Yeah so I go through the leaflets a lot with people. Erm . . . I, it's difficult for me because for some reason a lot of my caseload are over 35 and I know that the leaflets are, or were kind of generated for people kind of 14 to 35. But I still kind of hand them out to my patients because I think the medication one especially is excellent and to have a resource that we can give to people is really good. And I find that some of my ladies that are in their early 60s don't really want to go online, they want to read something in a booklet or a leaflet. So I've kind of given them in the caveat that these were designed for people in a younger age group but the information is still exactly the same and really relevant to them as patients under our service. And we also put the booklets in as part of our drop in erm so that people can kind of help themselves. So we've made them really accessible to people coming into our building as well. I give them to carers as well, the carers booklets have been really helpful'.

P09: 'RA: So are you currently using anything from the EYE-2 project?

P09: Erm a couple of leaflets. Erm . . . obviously I use the dialogue and QPR regularly but I know that the EYE-2 project used that as kind of a point of reference for progress. Erm the website I don't tend to use and the social group I've been attending and helping'.

P11: Yeah the booklets are really valuable. Erm especially at the beginning when someone is high risk and they are getting to know the care co-ordinator and it's kind of their triage assessment, having that kind of information in the booklets, I think the care co-ordinators have found them really helpful.

Referred patients to social group – NPT: Cognitive participation (activation)

P03: 'P03: Yeah, so as I said the main ones are the website and the erm, booklets and I do bear in mind the social group and refer patients or erm service users to that. Erm . . . I haven't currently got anyone that's attending the social groups erm . . . but yeah, I aware to refer people but it is the written resources that I use the most'.

P05: 'RA: So are you currently using anything from the EYE-2 project? I know you briefly mention about the social groups.

P05: All I know at the moment is the social groups . . . because I'm not a care co-ordinator, I mean they would know what they're using more specifically. But I know we are definitely using the social groups'.

P06: 'RA: what about the social groups?

P06: Yeah so the social groups were introduced by the research assistants and the researchers erm as they were when we tried to run them they were very poorly attended. Erm they use a lot of resource and trying to kind of plan them and go out and stuff and they are just very very poorly attended which is a shame'.

P07: 'RA: Do you use the website or the social group at all?

P07: So I have referred people to the social group but that seems like something that it more difficult to erm engage them into. But again it was the age the age that it was addressed to that was a barrier. Younger not wanting to do it because they don't want to be with anyone else but other younger people. Erm the group actually stood out for me more for younger people funnily enough . . . . I mean it's really nice, the social groups have actually developed into a . . . erm now there's a quite nice cooking activity and when it was COVID they became quite difficult. But these social groups certainly developed an interest but it seems not so much for the younger ones'.

P09: 'Okay so moving on what do you know or remember about the EYE-2 intervention approach and the resources so the website, the booklet and the social group?

P09: Erm so I was helping out with our local social group erm quite a bit. Erm and I think that that was quite a lot of fun for those involved and it was a useful resource for those who took part. Erm I've used a couple of the leaflets erm provided as well erm they've got really good information although targeted at a kind of younger audience aren't they'

'RA: Have you referred anyone to the social group out of your caseload?

P09: I have but unfortunately no one's taken me up on it haha'.

P10: 'Erm I guess I have a slightly different role in the team from care co-ordinators. Erm . . . and I think from what I've heard from my psychotherapy colleagues, erm when they've undertaking a piece of work and like the peer support group they think would be kind of beneficially to their client as well, then that's been something we've been able to recommend'.

Used website – NPT: Cognitive participation (activation)

P01: 'P01: The EYE-2 website has been promoted by sending out posters to service users'.

P03: 'RA: Is there anything you remember about the website?

P03: Yeah, I mean again use the website a lot. Erm . . . I consistently give out the website to people on my first visit with them. Erm, and often kind of, I never remember to save it but I often find myself googling Likemind and erm . . . when I'm in appointments with people, erm. The things I find particularly useful is the, I find . . . I find the 'what is psychosis' section you know a particularly useful resources. And I do go to that to guide that first discussion with people that have got you know first episode psychosis diagnosis or are kind of having an episode. Because I think kind of has got a nice level detail in terms of being you know informative enough without being overwhelming. So that one's really helpful and I also certainly refer people to the . . . erm, the kind of relatives and loved ones kind of stories and the recovery stories'.

P05: 'P05: Yeah I mean obviously the service users have been given the website and the leaflets have gone out. I think there's been some good use as well'.

P06: 'RA: Are you currently using anything from the EYE-2 project?

P06: Yes, I'm using the booklets and the website resources'.

P07: 'RA: What about the website?

P07: Not many people had a look at the website funnily enough but that's when I realised the importance of doing it together and that made a real difference to go through it together. Not right at the beginning but further down the line in session 5 or 6 to go to that'.

P08: 'P08: And then other service users that I've got that are within the EYE-2 range, I've given out the website and I've found that really useful as well.

RA: That sounds brilliant. That sounds really positive. So it there any kind of specific resources that you've started using then stopped or maybe any that you haven't used at all?

P08: Erm . . . no as I say I think the booklets are really great. I think plugging the booklets I should do some more definitely. Erm . . . I've got a couple of patients that are gamers so they're online a lot and they're used to being online erm and I know that they would maybe find looking at a booklet quite difficult, they would maybe chuck that in the corner of the room. So for them the website is really good and accessible'.

P11: Its useful to have the website and it's easy to navigate through so I think in that sense its quite helpful.

Revisits resources with patient – NPT: Cognitive participation (activation)

P01: 'P01: Giving . . . service users that awareness and carers that awareness of psychosis and how we can support. Erm so they'll be used like, and revisited. I can remember errm . . . there's a carer that's really struggled to understand psychosis, what is mean to the service user, what is means for like long term erm . . . prognosis and erm, I guess sort of the EYE-2 booklets and other things have been used sort of various times to try and sort of support the carer in particular around her sons mental health problems. She's really struggled with it, she's really struggles to accept that you know although . . . he can sort work and move on and recover but he might need to take medication for a prolonged period of time and still need, erm ongoing support. Cos you know, her view was that . . . erm he could take medication for a few weeks and the stop it again then he'd be alright and be able to move on and work and be able to function really well. But he is one of the service users that probably going to have long term mental health problems and erm need medication for a long time. And you know even now he's just recently had a hospital admission after coming off his again medication and this is probably his fourth or fifth admission, which is a a shame. But again it just about revisiting

the booklets and trying to go through it and explaining that need to carry on taking his medication . . . and it did work for a short period, but again stopped taking medication and stopped working. It's just that yeah, those booklets they'll use them for, you know those reasons, just to encourage and support. It's just a shame that for them in particular I think they're really struggling'.

P03: 'P03:I don't think I've come back to the same like early interventions booklet or those introductory booklets more than once but I've certainly come back to the treatment choices booklet a couple of times when we've been thinking about . . . because you know I might spend one session talking to somebody about medication options and then a different session talking to somebody about psychological therapy options or what have you. So I certainly would come back to that one but the other I think are good introductory ones but you sort of read them once, or I read them once with the client and then I leave them with them for them to go back to when they need them. Or likewise the website . . . the treatment choices one I find myself with a client saying 'do you remember that treatment booklet I gave you? Shall we get it out and have a look?' erm so that's, that the main one.

RA: Yeah that's really interesting. I guess if you feel that the other ones are more introductory you might not revisit them.

P03: And you know some of it they might not of got the first time so you might kind of refresh it but it doesn't, you know I would just tend people to do that for themselves really. Whereas there's so much in the treatment one that might guide a number of different discussions'.

P06: 'RA: So is it something that you try and revisit at different stages it sounds like with different resources?

P06: Yeah absolutely and kind of going back to it. So if we are thinking about treatment the we go back to the treatment booklet. You know if they are then going on about how they manage recovery then we will look at something else that might be helpful within the booklets or on the website that might be helpful. So yeah just keep going back to the resource, not just giving them out once and then leaving them'.

P08: 'RA: Do you ever revisit the resources with the service users or use them in a session with somebody rather than handing them out for people to go through independently?

P08: Yeah yeah, I've done that before as well. Again I think it depends on the patient and where they are in their recovery journey. Erm and how poorly they are as well. Sometimes it would be more appropriate to let them go away with the resource and go through it in their own time. But I have gone through it with the patients, particularly the medication one and sat and gone through it all. So it just sort of depends really'.

P09: 'P09: . . . The booklets for example, it really depends on the client to how I use it. So for some clients it can be really beneficial to go through it with them but then for others they prefer to go away and have a look through it in their own time and then come back if they have any questions'.

EYE-2 improves clinicians' knowledge – NPT: Coherence (internalisation)

P01: 'RA: Do you think there has been any benefits to the, you know, different clinicians in your team using the EYE-2?

P01: Yeah, I think . . . I think for those who were here from the beginning and sort of did that first erm . . . bit of training . . . erm, it think they've, I do think they've used the booklets regularly and that's been the big one. You know it has, it's just helped with guiding their practice a bit more'.

P02: 'RA: how do you feel the EYE-2 approach and materials have changed the way you work and the team works?

P02: It's been such a long time it's difficult to remember what it was like before. Erm . . . I mean they're useful even for staff. Erm, we've got a lot of staff that either come to use newly qualified or you know they've been qualified for a while but don't have any community experience and again instead of us trying to explain . . . what we do and what's on offer

to them we've kind of just put the EYE-2 resources into their induction packs. And it helps them as well. So it's kind of, we use it in every . . . bit of the service that we offer including training staff'.

P03: 'RA: Do you feel that there have been any benefits to you as a clinician having worked with the EYE-2 over the past couple of years?

P03: Yeah, I mean again I . . . I feel that it has, like some of the information in the booklet . . . some of the treatment options I wasn't aware of, so I was able to go away and have a look at those'.

P05: 'RA: Do you feel that the EYE-2 has helped you learn anything in particular?

P05: Yeah definitely. Erm when I went through one of the booklets with a service user, it really made sense the way that it was worded and sometimes these things can be a bit wordy. So it's about bringing it back to how someone will understand it'.

P07: 'RA: So do you think the EYE-2 has helped you learn anything in particular?

P07: Erm what have I learnt? Erm so definitely about the importance of timing and when to introduce things with a patient because that could really influence whether the person engages with the materials. Erm what else have I learnt? . . . yeah I would say that was the main thing that timing is key'.

P11: Yeah so I think it's always good to have extra resources in place and I think it's always good to know you can go back to the resources with the clients and you can kind of go back to it when you need it. I think it's kind of reinforced some of our staffs knowledge as well, especially I think it could be good for the people new to the team . . . but I've worked in EIP for like seven years so it's kind of what I already knew but they are still really helpful for service users to use.

Introducing at the start of treatment – NPT: Coherence (individual specification)

P01: 'P01: So, initially erm, when we were sending out, cos we send out an introduction letter to the service and they were sending out booklets with the introduction letter. But I think that practitioners now tend to . . . depending on which service user it is and depending on how responsive they are they might take out one or two at a time and actually work through them with a service user and guide. Other times they'll just take them out and sort of let the service user go through them in their own time, and do it with the carer as well and to encourage the carer to go through it with the service user'.

P02: 'P02: Erm I know the written resources have been really really useful. We've built them into our kind of initial packs. So we give them out to people when they are accepted. Some are more generic mental health problems, so we take them out on assessment because it doesn't necessarily suggest that somebody's got psychosis'.

P03: 'RA: How would you decide erm when do you decide what materials to use?

P03: Erm, I would usually start off . . . erm an interaction with a new patient or a new service user using the materials. I really, I really find it helpful thing to be able to go on the first visit and give them the, erm, early intervention the kind of what is early interventions booklet and also the carers booklet. And usually I just give those two to start with as an introduction and then within a few sessions when we start to get a bit more into the details I might give them also the treatment choices one. I may give them all at once but I don't, I do try and stagger it as to not overwhelm people'.

P04: 'RA: So how and when would you decide to use them with a service user?

RA: Erm . . . so ideally it would be at the being of the persons time with the team and we've found it most effective when we've had like a little stand with all the leaflets in, in one of the main offices and then when the care co-ordinators are on their way to see someone for the first time they can just grab one to give them'.

P06: 'RA: So how might you introduce that to a new service user that you are working with?

P06: Erm I guess it depends on the service user and where they are in their journey. Erm I suppose that is about human judgement and assessing when to introduce that. But I would like to introduce it early as possible. Erm kind of when we do that talk about why we are there, like when they're like 'well I don't have psychosis so I don't know why you are here' and then it's about that psychoeducation. So it's used at every stage of someone's journey cos actually the resources are there at every stage and aspect of their journey because they're there when you are considering treatment and when you're thinking about what is psychosis to how does this impact on my family or how can I help someone. So actually the resources are helpful for every part of the patient journey and you can introduce them when appropriate. And I think it is dependent on where your service user is in their journey and where their families are in that journey as to what booklet you introduce, when you introduce the website. But we try to do that as early as possible'.

P09: 'RA: When do you decide to introduce these resources to a client or a service user?

P09: Erm I think that depends on the care co-ordinator. So I personally I like to get information out as soon as possible but it depends how you are working with a client as well. Sometimes people need a drip feed approach and by sort of shoving these booklets in their face might not be the best approach haha'.

Utilised treatment choices booklet – NPT: Coherence (internalisation)

P01: 'P01: I think the leaflets have been invaluable, they've been excellent. We've, you know we've used them regularly, erm you know I'll be honest as well, we've actually used them with over 35s as well as an introduction to . . . psychosis, and Early Intervention for Psychosis teams and the sort of possible treatments available. And they've been really well received by service users and carers . . . yeah so they've been an excellent resource'.

P03: 'P03: Yeah sometimes I do use it with existing service users if they have a particular question or we are considering a change in treatment approach or something like that then I might whack out the erm, treatment options one'.

P04: 'P04: Erm . . . . I think the one, So there's one for carers, one for service users and one for medications, what's the other one?

RA: Is that the treatment choice one?

P04: I think that's the one I'm thinking of for medications. I think the one we use the most is the one for service users but I think also the really big thick one is really helpful as well I think'.

P06: 'RA: So is it something that you try and revisit at different stages it sounds like with different resources?

P06: Yeah absolutely and kind of going back to it. So if we are thinking about treatment the we go back to the treatment booklet. You know if they are then going on about how they manage recovery then we will look at something else that might be helpful within the booklets or on the website that might be helpful'.

P09: 'RA: You said that you've been using some of the leaflets, could you tell me which ones you've been using or have found most useful?

P09: Erm so the treatment one I've been using. That's been quite helpful to kind of educate the patients on what options and choices they have in their treatment'.

P11: Erm yeah the booklets are really valuable. Erm especially at the beginning when someone is high risk and they are getting to know the care co-ordinator and it's kind of their triage assessment, having that kind of information in the booklets, I think the care co-ordinators have found them really helpful.

Staff conversations around EYE-2 – NPT: Collective action (interactional workability)

P07: 'RA: So thinking about your team, how do the attitudes of staff, service users and carers towards the EYE-2 influence whether they're used?

P07: Erm . . . the discussions in meetings, that has really helped us reflect on that. And the training weas helpful, the booster session was helpful. I think that was a really good approach to have a booster session . . . erm what else was there. Erm well I think it's just again to have the weekly section in the MDT meeting to talk about the EYE-2. And we could definitely tell from the amount of brochures that they were going out.

RA: Okay so what do you do to help others to use the approach and resources? Have you introduced any new staff at all to the approach and resources?

P07: Yeah as a supervisor I do introduce people to it and that's the first thing actually that I give to care co-ordinators to introduce them to it and ask them to familiarise themselves with it. Erm and its actually quite nice for staff that are new to EIS to actually have that. Erm, so not only for patients but also for new starters in the trust or to our services. So that was really well received'.

P08: 'RA: What else could be provided to help you know more about how to use the EYE-2 approach and resources?

P08: Erm I think it's just keeping it fresh in people's minds. Just kind of talking about it in team meetings. We've had some really good assistants. =Team RA = the lady that's kind of been working with us on the EYE-2, she's kind of been really present in team meetings which I think is really important to kind of keep it alive'.

P10: 'P10: I mean again I'm thinking within my kind of most immediate contacts . . . erm you know with the pandemic I think I've been having kind of less contact with my colleagues. Erm and it affects us social within the team. Erm when I saw my colleagues actually within work . . . erm it could be sort of thought as almost corridor conversations and that's something that I just think doesn't having in the same way. Erm and I do sometimes try and make a point of calling people on teams to just have kind of an informal convo but I think it just ends up kind of feeling formal anyway. Rather than if you were kind of just wandering around the office. Erm I think talking about resources, I think that's the kind of thing that just kind of comes up in more informal office conversations, in terms of work anyway'.

Staff turnover – Process limiting factor

P1: 'I think because we've had changes in the team, we've had new staff starting and that's, it's hard for them because they didn't come in at the beginning'.

P2: 'What else could be provided to help you to know more about using the EYE-2 approaches and resources?

P2: I think potentially, I mean I don't know if it's, I guessing its largely due to COVID, I think . . . in line with us having such a high staff turnover and everything that's happened in the last 18 months. I think it's been really easy to use the written resources, they've been really useful and really handy but I think for the rest of it, maybe having . . . a link person some in . . . or have a bit more contact from somebody from EYE-2 just to remind us what there is. Erm and like I say kind of refresher training or kind of rerunning the training when we got new staff would have been helpful'.

P3: 'Do you do anything to help others to use the approach and resources or have you introduced any new staff to the approach and resources?

P3: Yeah certainly. I think that we have had quite a high staff turnover since we first started the trail and erm you know new members when they start the team and have their inductions, which you know is something I'm a little bit involved in, sort of mentoring new staff members'.

P5: 'So what about the attitudes of staff towards the EYE-2?

P5: Again I think it's just down to them understanding what it is. You know the trouble with these projects is that people often come and go so sometimes you don't get the best relationships because it's such a small time is spent in one team and then they move on and we get somebody else. Erm so I think again it's about introducing themselves before they arrive, rather than just the first day they arrive. And again a lot of the staff are new, you know they're not up to speed with what EYE-2 is'.

P11: 'We've had a lot of turnover and people coming back from erm . . . and we've had a lot of new starters. About four actually just starting in the last month, which is good actually but I wonder if they might need a refresher or maybe they aren't aware of it. that would be good, I don't know if you could come back and do another training.

P11: We also have a new manager so I'm not sure they're aware. Erm because obviously people would normally ben prompted by their manger so maybe it's something I need to email them about'.

Found resources helpful – Individual/communal appraisal

P01: 'What do you know or remember about the EYE-2 intervention approach and resources? So the website, the leaflets and the social group resources?

P01: The . . . erm I mean, I think the leaflets have been invaluable, they've been excellent. We've, you know we've used them regularly, erm you know I'll be honest as well, we've actually used them with over 35s as well as an introduction to . . . psychosis, and Early Intervention for Psychosis teams and the sort of possible treatments available. And they've been really well received by service users and carers . . . yeah so they've been an excellent resource'.

P02: 'Are you currently using anything from the EYE-2 project?

P02: Yeah, all the booklets and the outcome measure packs.

RA: Okay, perfect. Yeah, so is there any booklets you use more or erm . . . stand out to you as being the most helpful?

P02: They're genuinely all really useful, we use all of them. We kept running out so we've had to order some more, haha'.

P03: 'Is there anything you remember about the website?

P03: Yeah, I mean again use the website a lot. Erm . . . I consistently give out the website to people on my first visit with them. Erm, and often kind of, I never remember to save it but I often find myself googling Likemind and erm . . . when I'm in appointments with people, erm. The things I find particularly useful is the, I find . . . I find the 'what is psychosis' section you know a particularly useful resources. And I do go to that to guide that first discussion with people that have got you know first episode psychosis diagnosis or are kind of having an episode. Because I think kind of has got a nice level detail in terms of being you know informative enough without being overwhelming. So that one's really helpful and I also certainly refer people to the . . . erm, the kind of relatives and loved ones kind of stories and the recovery stories'.

P04: 'Is there anything that you remember about the website or the social group resources at all?

P04: I don't really remember anything about the website to be honest. Erm . . . and in terms of the social group, I know initially it was really helpful but obviously it was massively impacted on by the pandemic. But yeah I know initially I think it was a peer led social group and it was really popular but I guess my impression is that perhaps it's been harder to facilitate because of the pandemic, not that that should be an obstacle for it continuing . . . I think now, I don't even know if it's restarted to be honest or what's happening with the current EYE-2 social group. . .

RA: Okay great. Are you currently using anything from the EYE-2 project?

P04: Erm . . . I think we are still using some of the leaflets, I think we still have some of the leaflets lying around.

RA: Okay great, any specific ones that you use, so there's the four different booklets or leaflets . . . any specific ones that you use more or less?

P04: Erm . . . . I think the one, So there's one for carers, one for service users and one for medications, what's the other one?

RA: Is that the treatment choice one?

P04: I think that's the one I'm thinking of for medications. I think the one we use the most is the one for service users but I think also the really big thick one is really helpful as well I think'.

P05: 'Do you feel there have been any benefits to you as a clinician having worked with the EYE-2 over the past couple of months or years?

P05: Erm well I am a clinician because I'm a nurse but erm . . . yeah it was helpful going through the booklet and it was certainly helpful for one of the service users that I co-work with for the social groups'.

P06: 'So you've kind of touched on this a little bit but what do you know or remember about the EYE-2 intervention approach and resources?

P06: Erm so you've got the different booklets. Erm kind of booklets for carers as well which was really helpful. Erm you've also got the kind of outcome measures, the dialogues and the HoNOS measures to kind of look at someone's recovery journey and whether that's been helpful and looking at engagement and kind of seeing whether introducing resources early helps engagement.

RA: Yeah that sounds brilliant. So is there anything else that could be provided to you to help you know more about using the EYE-2 approach and resources?

P06: No I really like the website. It's a really helpful tool to use and to get people to look at it in their own time because I think sometimes giving people loads of pamphlets and leaflets can kind of overwhelm people. Erm yeah so not that I can really think of'.

P07: 'What do you know or remember about the EYE-2 project training?

P07: Erm yes so I suppose it focused on the intervention that we are providing and EIS and also the handouts to give us a better understanding of what is to offer. Also about motivational interviewing styles to engage people in interventions. Er yeah so it was really helpful to to use. Also kind of the the the additional things such as the carers [inaudible segment] which was really helpful. Erm what else was there? Erm erm the outcome measures to use the regularly, obviously the outcome measures help the study. It also helps us because obviously we are meant to do them anyway so it was really helpful to push ourselves to meet the deadlines of these outcome measures. We should be doing the anyway but its yeah, we also need to collect a lot of data from the management side to prove that we are delivering what we are meant to be delivering. But it's good to push that to have the understanding, it is needed to understand how the intervention is being delivered and what outcome they have'.

P08: 'What do you know or remember about using the EYE-2 approach and resources?

P08: So the leaflets, the website erm brilliant. They are really really helpful. The social groups, we never actually had any social groups and I can remember the social groups being discussed in the training and I remember we thought that would be a really good part of it and for some reason that never quite took off'.

P09: 'You said that you've been using some of the leaflets, could you tell me which ones you've been using or have found most useful?

P09: Erm so the treatment one I've been using. That's been quite helpful to kind of educate the patients on what options and choices they have in their treatment'.

P10: 'What do you know or remember about the EYE-2 intervention approach and resources?

P10: Erm so I guess I kind of think about it in three ways really. Erm so you've got the website, which is available for people to use. Erm I think that's very important especially in the context of a pandemic. Erm it means that information is a lot more accessible and can be updated. Erm and quite often kind of contacting a service a website is the easiest way, rather than trying to get hold of a person to actually speak to. The other aspects of it are the kind of paper resources, the information . . . erm I think it's incredibly helpful I think. You know I think sort of predating the information that you've developed, which is more kind of colourful and well developed more so than I guess previous information we had available. So having it on paper is really helpful when we have face-to-face contacts. The thing I guess that I'm not aware of is if they're kind of electronic as well. Erm maybe you can kind of access them through the website but it's something I guess I haven't used so much in my role, kind of since we started seeing people less and less face to face'.

P11: 'Erm yeah the booklets are really valuable. Erm especially at the beginning when someone is high risk and they are getting to know the care co-ordinator and it's kind of their triage assessment, having that kind of information in the booklets, I think the care co-ordinators have found them really helpful'.

Appendix 10 Response to National Health Service England Webinar

TABLE 51 Distribution of EYE-2 trust performance across all 55 NHS Trusts

	Top 1–10 trusts	Top 11–20 Trusts	Top 21–30 Trusts	31–40th Trust	21st–50th trust	51–55th trust
Waiting time	*	*	*	**	***	
CBT access	*		****	****		
FI access	*	*	**	****	*	
Clozapine		***	**	**	*	*
Employment support	*	****	*		**	*
Physical health screen		*	**	***	***	
Physical health intervention	*	*	**	**	**	*
Carer support		***	****	*	*	

Note
Each * represents the position of one of the 9 EYE-2 trusts.

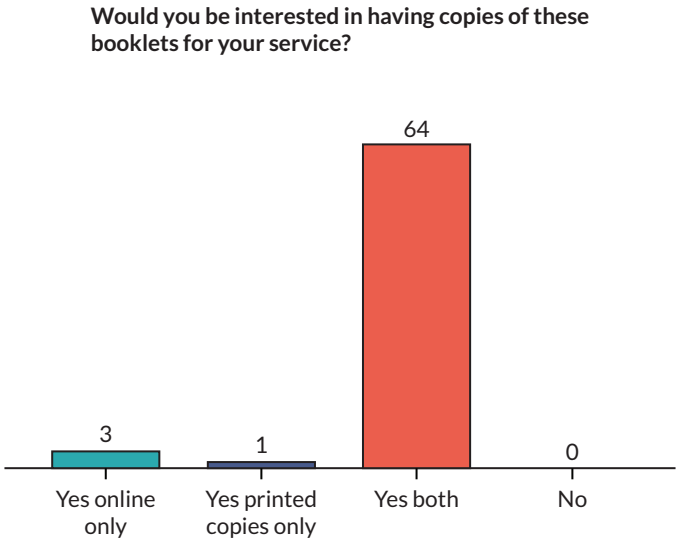

FIGURE 30 Numbers of service leads wanting copies of the EYE-2 booklets for their services.

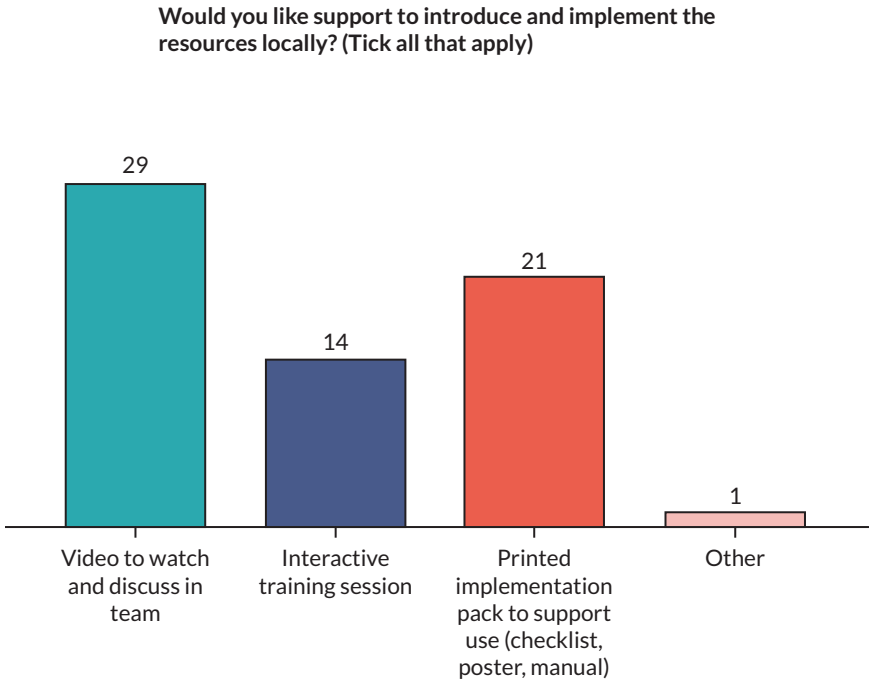

FIGURE 31 Support requested to implement the use of resources locally across England.

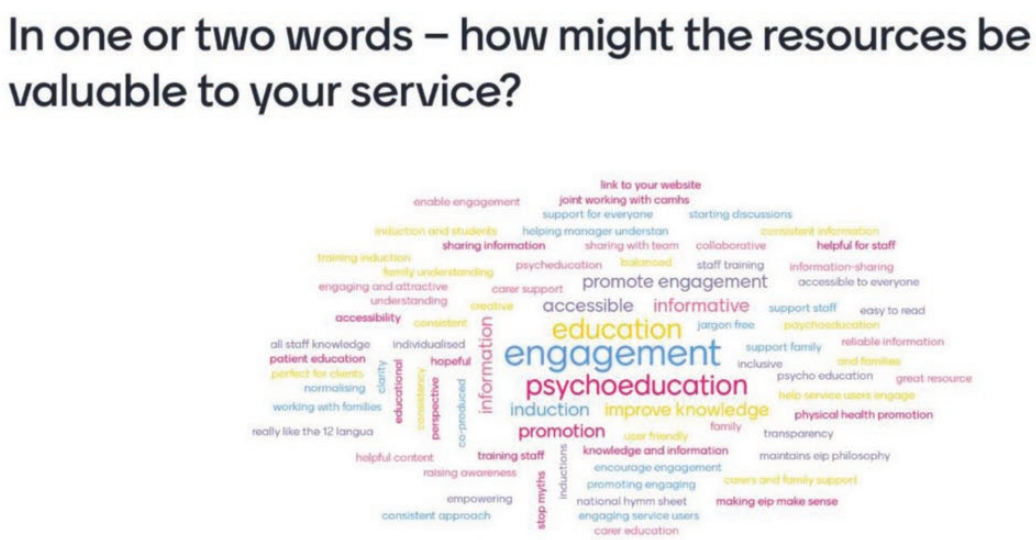

FIGURE 32 Word cloud of how the resources might benefit services.

EME
HSDR
HTA
PGfAR
PHR

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